EXHIBIT A

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

~~FWK HOLDINGS, LLC, on behalf of itself and all others similarly situated,~~ ~~Plaintiff,~~ ~~v.~~ ~~SANOFI-AVENTIS U.S. LLC,~~ ~~Defendant.~~	~~Civil Action No. 16-cv-12652-ADB~~
~~CESAR CASTILLO, INC., on behalf of itself and all others similarly situated,~~ ~~Plaintiff,~~ ~~v.~~ In re: LANTUS DIRECT PURCHASER ANTITRUST LITIGATION ~~SANOFI-AVENTIS U.S. LLC,~~ ~~Defendant.~~	~~Civil Action No.~~Nos. 16-cv-12652 (JGD) 17-cv-10042~~-ADB~~ (JGD) Leave to File Granted on: February 20, 2018 [ECF No. 50]

SECOND AMENDED CLASS ACTION COMPLAINT
AND DEMAND FOR JURY TRIAL

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I. INTRODUCTION

1. The plaintiffs, FWK Holdings, LLC and César Castillo, Inc., on behalf of themselves and all others similarly situated, for their complaint against the defendant, Sanofi-Aventis U.S. LLC, allege the following based on (a) personal knowledge, (b) the investigation of counsel, and (c) information and belief.

2. This is a civil antitrust action challenging the defendant's unlawful impairment of competition in the market for injectable insulin glargine ~~for injection~~. Sanofi used a variety of anticompetitive practices as part of an overall scheme to block follow-on competition for its branded insulin glargine ~~products~~product, Lantus ~~and Lantus SoloSTAR~~. The plaintiffs and the class of direct purchasers on whose behalf this action is brought were harmed by Sanofi's unlawful monopolistic acts.

3. ~~Sixteen~~Eighteen years ago, on April 20, 2000, the U.S. Food and Drug Administration ("FDA") approved insulin glargine as a long-acting analog insulin for management of diabetes. By May 2001, Sanofi was commercially selling vials and injector cartridge formulations of the drug in the U.S. under ~~the trademark Lantus (and later as Lantus~~ SoloSTAR, another. In 2007, Sanofi began selling Lantus in an injector pen ~~formulation).~~packaging under the name "Lantus SoloSTAR." In August 2014, ~~–~~ when Lantus had already been on the market for *thirteen* years – the Sanofi patent that claimed insulin glargine and disclosed the components of its formulation expired~~; six.~~ Six months later, on February 12, 2015, the "pediatric exclusivity" attached to that patent also expired. That ended Sanofi's lawful exclusivity for insulin glargine. By then, Sanofi had ~~enjoyed~~made many billions of dollars in sales based on that compound. At that point, under operation of law, the invention of insulin glargine passed into the public domain, and follow-on competition from

other insulin glargine products should have ~~been permitted to enter~~entered the U.S. market, just as it had elsewhere around the world.

4. Eli Lilly and Company, a leader in pharmaceutical products, and a long-time supplier of ~~insulins~~insulin products to diabetic patients worldwide, sought to do just that. For years – and working with its development partner Boehringer Ingelheim – Lilly developed a follow-on insulin glargine product for worldwide distribution. In 2013, it filed with the FDA a New Drug Application for approval to sell insulin glargine in a pen in the U.S. beginning in February 2015,

i.e., upon expiration of the U.S. insulin glargine patent and its pediatric exclusivity. Pharmacoeconomics teaches that a second insulin glargine product would have launched at a lower price, and driven down the price of insulin glargine.

5. But Sanofi had erected a regulatory roadblock by unlawfully listing *other* patents in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the "Orange Book") that either did not belong there, or did not ~~even~~ cover all Lantus formulations; ~~the false~~these improper filings required Lilly to inform Sanofi ~~of~~about Lilly's efforts to gain FDA approval. Because Sanofi listed these patents in the Orange Book, though, Sanofi could ensure that, when Lilly sought to make an insulin glargine product, Sanofi could sue and automatically delay the FDA's approval of Lilly's competing insulin glargine product for at least two and a half years. And by suing, Sanofi could create an opportunity to leverage that suit – however meritless – into a settlement with Lilly delaying competition.

6. Lilly provided Sanofi with confidential documents identifying the active and inactive ingredients of Lilly's insulin glargine product and ~~an~~Lilly's proprietary injector pen (which had been sold for years with other insulin products) by which it may be administered.

The documents showed the Lilly insulin glargine injector product did not infringe any of the Sanofi patents actually claiming ~~its~~the drug product Lantus ~~products~~.

~~6~~7. Sanofi sued Lilly anyway ~~on~~, asserting two patents ~~disclosing examples of~~that disclosed insulin glargine formulations ~~in which~~containing a different ingredient, polysorbate 20 or 80~~, was added~~. (Sanofi had begun adding polysorbate 20 to *vials* of Lantus in around 2005, ~~though the Lantus~~but not to insulin glargine in its injector pens ~~remained unchanged~~and cartridges).

8. Sanofi also asserted two patents issuing from an application filed over 10 years ~~prior~~earlier by its partner, a British design company, directed to ~~an~~Sanofi's SoloSTAR injector pen ~~different from Lilly's~~. These pen patents did not claim insulin glargine; nonetheless, Sanofi had earlier improperly submitted information about these pen patents to the FDA for listing in the Orange Book, creating yet another unnecessary hurdle for Lilly and other would-be generic competitors.

~~7~~9. Sanofi's suit lacked any reasonable basis. But merely by ~~bringing the claims~~claiming that Lilly infringed patents listed in the Orange Book, Sanofi caused a 30-month delay of FDA approval of Lilly's NDA for insulin glargine. This 30-month delay, extending beyond the February 2015 expiration of ~~exclusivity from the Sanofi~~Sanofi's lawful monopoly over insulin glargine ~~patent~~, prevented Lilly from marketing its own insulin glargine drug product.

~~8~~10. Eventually, Sanofi and Lilly settled the suit over the U.S. patents~~, but~~. But by then Sanofi's scheme to delay Lilly's efforts to gain U.S. market entry had worked. Sanofi granted Lilly a *global* license to sell the Lilly injector insulin glargine product ~~worldwide~~everywhere else in the world, but delayed competition from Lilly's product ~~would~~

~~not begin~~ in the U.S. until December ~~of~~ 2016, almost two years after the technology for insulin glargine had become publicly available for use by Lilly and others in this country.

11. Even after delaying Lilly's market entry for nearly two years, Sanofi continued to erect roadblocks to competition in the market for Lantus and insulin glargine. It continued to stack up patents covering the SoloSTAR packaging – submitting *thirteen more* for listing in the Orange Book – and launched patent infringement suits against not one but two other would-be competitors. Simply by filing those suits (which were just as meritless as Sanofi's suit against Lilly), Sanofi triggered regulatory stays that is delaying full competition in the Lantus and insulin glargine market lasting at least into 2020.

~~9~~12. Were it not for Sanofi's unlawful Orange Book listings and its baseless suit against Lilly, follow-on competition from insulin glargine products would have ~~commenced~~started on or soon after the mid-February 2015 expiry of ~~the~~Sanofi's *lawful* monopoly over insulin glargine. ~~For a market where the gross revenues topped well over $7 billion in 2014 alone, the savings to American purchasers of insulin glargine would have far exceeded a billion dollars.~~

~~10~~13. This suit, brought under federal antitrust laws, seeks to recover the overcharges sustained by direct purchasers of Lantus and Lantus SoloSTAR as a result of Sanofi's unlawful and anticompetitive practices. Given that gross revenues topped $7 billion in 2014 alone, the overcharges to direct purchasers likely amount to hundreds of millions of dollars.

II. PARTIES

~~11~~14. The plaintiff, FWK Holdings, LLC ("FWK"), is a corporation organized under the laws of the State of Illinois, with its principal place of business located in Glen Ellyn, Illinois. FWK is the assignee of the claims of the Frank W. Kerr Co., which, during the class

period, as defined below, purchased Lantus and ~~Lantus SoloSTAR, and~~ would have purchased Lilly's competing insulin glargine product, had it been available.

~~12~~15. The plaintiff César Castillo, Inc. ("CCI") is a corporation organized under the laws of the Commonwealth of Puerto Rico, with its principal place of business and headquarters located at Bo. Quebradas Arena, Rd. #1 Km. 26.0, Rio Piedras, Puerto Rico, 00926. During the Class Period, CCI purchased Lantus ~~and Lantus SoloSTAR~~ directly from the defendant, and would have would have purchased Lilly's competing insulin glargine product, had it been available.

~~13~~16. The defendant Sanofi-Aventis U.S. LLC ("Sanofi," or, where necessary to distinguish it from an affiliate, "Sanofi U.S.") is a Delaware limited liability corporation with its principal place of business located at 55 Corporate Drive, Bridgewater, New Jersey 08807.

III. JURISDICTION AND VENUE

~~14~~17. This action arises under section 2 of the Sherman Act, 15 U.S.C. § 2, and section 4 of the Clayton Act, 15 U.S.C. § 15(a), and seeks to recover threefold damages, costs of suit, and reasonable attorneys' fees for the injuries sustained by the plaintiffs and members of the class resulting from Sanofi's unlawful monopolization of the United States market for insulin glargine. The Court has subject matter jurisdiction under 28 U.S.C. §§ 1331(a) and (d), 1337(a), and 15 U.S.C. § 15.

~~15~~18. Venue is appropriate within this district under 15 U.S.C. §§ 15(a), 22 (nationwide venue for antitrust matters), and 28 U.S.C. §1391(b), (c), and (d) (general venue provisions).

~~16~~19. Sanofi transacts business within this district, transacts its affairs and carries out interstate trade and commerce in substantial part in this district, and/or it or its agents may be found in this district.

~~17~~20. Sanofi's conduct was within the flow of, was intended to, and did have a substantial effect on, interstate commerce of the United States, including in this district.

~~18~~21. During the class period, Sanofi manufactured, sold, and shipped Lantus and Lantus SoloSTAR in an uninterrupted flow of interstate commerce.

~~19~~22. During the class period, Sanofi or one or more of its affiliates used the instrumentalities of interstate commerce effectuate the scheme. The scheme in which Sanofi participated had a direct, substantial, and reasonably foreseeable effect on interstate commerce.

~~20~~23. This Court has personal jurisdiction over Sanofi. Sanofi has transacted business, maintained substantial contacts, and/or committed overt acts in furtherance of the illegal scheme throughout the United States and including in this district. The scheme was directed at, and had the intended effect of, causing injury to persons residing in, located in, or doing business throughout the United States, including in this district.

IV. INDUSTRY BACKGROUND

~~21~~24. Branded drug companies can and do obtain valid patents that cover their new prescription drug products. Such patents encourage ~~discovery~~innovation and development of new medicines~~, providing~~. They provide protection from competition by other drug companies for a length of time set ~~under a statute~~ by Congress.

~~22~~25. Once the lawful periods of exclusivity expire on brand products – once the disclosures in the brand company's patent enter the public domain – companies seeking to market generic drugs, follow-on ~~biologics~~products, or biosimilar products can seek FDA approval to sell competing identical or similar versions of the brand, allowing those companies to manufacture products that are just as safe and effective, but less expensive, than the brand.

The medication becomes more affordable for purchasers, who are no longer burdened by the high cost of the brand drug.

~~23. Brand companies are required to provide to the FDA information about patents claiming their particular drug product. The FDA – relying completely on the information provided by the brand – must list those patents publicly, so that competitors understand the scope of the brand's ostensible patent protection. Would-be competitors must wait until the expiration of all listed patents, unless they can certify that their product does not infringe one or more listed patents. Such a certification may trigger the brand company to sue for patent infringement – but a brand company may do so only if it has an objectively reasonable basis to claim the patent's protection. The listed patents, would-be competitors' certifications, and brand company's suits all affect the timing of FDA approval for less-expensive products.~~

~~24~~26. Branded drug companies thus have a statutory period of time to charge very high prices for medications that~~, in fact,~~ often cost little to manufacture. But it is a limited period, after which would-be competitors may enter the market with lower-cost ~~substitutes~~competing products. And the timing of approval of these competing products depends on, among other things, the truthfulness of the patent information provided by the brand to the FDA.

27. A company must identify and ask the FDA to list certain types of patents – patents covering the drug product and methods of use – in the Orange Book. The FDA is required by law to list any patents that are identified, and does not (indeed cannot) evaluate for itself whether those patents can be listed. Once any patent is listed, a would-be competitor must notify the brand company if the competitor intends to make a follow-on product. That gives the

brand company the opportunity to sue and, by suing, delay FDA approval of the competing product for two and a half years.

~~25~~28. From this industry framework, two rules emerge. First, brand drug companies cannot provide false or misleading patent information to the FDA and wield that information to delay entry of medications containing the same molecule as the brand product beyond the expiration of legitimate patent protection. Second, drug companies cannot file patent infringement lawsuits against would-be competitors when the action has no realistic likelihood of success of the merits; the mere filing of such a lawsuit stalls legitimate efforts to gain market entry.

~~26~~29. Sanofi broke both rules.

A. The regulatory structure for approval of brand and generic drugs.

~~27~~30. The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 *et seq.* ("FDCA"), governs the manufacture, sale, and marketing of prescription pharmaceuticals in the United States.

1. Approval pathways available to pharmaceutical products.

~~28~~31. During the periods relevant here, § 505 of the FDCA described three pathways for approval of drug applications: (1) an new drug application ("NDA") that contains full reports of investigations of safety and effectiveness (§ 505(b)(1)); (2) an application that contains full reports of investigations of safety and effectiveness but where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference (§ 505(b)(2)); and (3) an abbreviated new drug application ("ANDA") that contains information to show that the proposed product is identical in active ingredient, dosage form, strength, route of

administration, labeling, quality, performance characteristics, and intended use, among other things, to a previously approved product (§ 505(j)).

a. Approval of new drugs under section 505(b)(1).

~~29~~32. Under the FDCA, the manufacturer of a new drug must obtain FDA approval to sell the drug by submitting a New Drug Application ("NDA").[1] An NDA must contain scientific data demonstrating that a drug is safe and effective. New drug applicants, however, are not required to, and usually do not try to, show that their new drug product is superior to another similar, already approved, product.

~~30~~33. After FDA approval, the NDA holder may list in the Orange Book any patents that (i) claim the drug or a method of using the drug, and (ii) reasonably could be asserted against a would-be competitor seeking to make, use, or sell a competing version of the brand drug. If patents issue after approval, the manufacturer may list them in the Orange Book within 30 days of issuance.[2]

~~31~~34. The FDA relies completely on the brand manufacturer's truthfulness about whether a patent claims the drug product or a method of using the drug product, and about whether an infringement claim could reasonably be asserted against a competitor – i.e., whether the patent is valid, enforceable, and actually claims the NDA product or a method of using it. The FDA does not have the resources, specialization, or legal authority to verify the manufacturer's ~~patents~~patent submissions for accuracy or trustworthiness. In listing patents in the Orange Book, the FDA performs ~~merely~~ a ministerial act. The FDA does not exercise judgment on performing this mechanical task.

[1] 21 U.S.C. §§ 301-392.

[2] 21 U.S.C. §§ 355(b)(1) & (c)(2).

b. Approval of generic drugs under section 505(j).

~~32~~35. In 1984, Congress amended the FDCA with the enactment of the Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984), commonly referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments added to the FDCA two pathways to approval intended to expedite the availability of ~~lower-cost~~lower-cost alternatives to expensive brand drugs – one for generic products, and one for brand products similar to an already approved drug.

~~33~~36. First, the Hatch-Waxman Amendments simplified the regulatory process for generic manufacturers. Previously, generic applicants had to follow the same steps as an applicant filing an NDA, including costly and time-consuming clinical trials to establish safety and efficacy. This delayed approval of generic drugs, or deterred companies entirely from manufacturing generic drugs, and deprived drug purchasers of the benefit of generic competition.

~~34~~37. But under the Hatch-Waxman Amendments, a manufacturer seeking approval to sell a bioequivalent generic version of a brand drug can file an Abbreviated New Drug Application ("ANDA"). An ANDA relies on the scientific findings of safety and effectiveness included in the brand manufacturer's NDA. The ANDA filer only needs to show that its generic drug is bioequivalent to the brand drug. Bioequivalence means that the generic product delivers the same amount of the same active ingredient into a patient's blood stream for the same amount of time as does the corresponding brand drug, and hence has the same clinical effect.[3]

~~35~~38. The FDCA and Hatch-Waxman Amendments operate on the principle that bioequivalent drug products are therapeutically equivalent, and may therefore be substituted for one another.

[3] 21 U.S.C. § 355(j)(8)(B).

bioequivalent drug products are therapeutically equivalent, and may therefore be substituted for one another.

c. Approval of drugs under section 505(b)(2).

~~36~~39. Second, the Hatch-Waxman Amendments permitted brand drug companies to streamline the NDA process by relying on ~~already-conducted~~ scientific studies already conducted for an approved drug, rather than incurring the expense and burden of redoing the ~~study~~studies from scratch. This is the third pathway for drug approval – through § 505(b)(2) of the Act.

40. Section 505(b)(2) may be seen as an amalgam between § 505(b)(1) NDAs and § 505(j) ANDAs.~~37.~~ A § 505(b)(2) application is a new drug application (NDA). But, unlike § 505(b)(1) drug applications, applications submitted under this pathway need not contain voluminous, expensive studies, and data newly developed by the drug sponsor.

~~38~~41. Section ~~§~~ 505(b)(2) expressly permits FDA to rely, for approval of an NDA, on data not developed by the applicant.[4] A § 505(b)(2) application is one for which one or more of the investigations relied upon by the applicant for approval "were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted."[5] So the FDA may to look to studies conducted on an already-approved brand product to support approval of a new NDA.

~~39~~42. When the applicant seeks to use studies from another product, reliance on that information (whether a previously approved product or from published literature) must be scientifically appropriate. An applicant needs to provide a scientific "bridge" to demonstrate the

[4] Sections 505(b)(2) and (j) together replaced FDA's paper NDA policy, which had permitted an applicant to rely on studies published in the scientific literature to demonstrate the safety and effectiveness of duplicates of certain post-1962 pioneer drug products (*see* 46 Fed. Reg. 27396 (May 19, 1981)).

[5] 21 U.S.C. § 355(b)(2).

relationship of the referenced and proposed products. For example, the applicant may conduct bioavailability or bioequivalence studies to establish a bridge, and establish that the proposed product is a pharmaceutical alternative.

~~40~~43. ~~Pharmaceutical alternatives~~These § 505(b)(2) products are drug products that contain the identical therapeutic ingredient, but not necessarily in the same amount, dose, or form. A pharmaceutical alternative is held to the same standards of identity, strength, quality, and purity, including potency and, where applicable, content uniformity, disintegration times and/or dissolution rates.[6]

~~41~~44. Generally, any differences in rate and extent of absorption should be reflected in the labeling of the § 505(b)(2) product. The proposed product does not need to be shown to be clinically better than the ~~previously-approved~~previously approved product. Nor does it need to be bioequivalent. ~~A § 505(b)(2) application would be appropriate for a controlled-release product that is not bioequivalent to an already-approved drug where the proposed controlled-release product is at least as bioavailable as the approved product, or where the pattern of release of the proposed product is at least as favorable as the approved pharmaceutically equivalent product.~~[7]

~~42. In 2010, Congress passed the Biologics Price Competition and Innovation Act (BPCIA) to establish a fourth pathway for FDA drug approval for "biosimilar" drugs. But this~~

[6] 21 C.F.R. § 320.1(d).

[7] In 2010, Congress passed the Biologics Price Competition and Innovation Act (BPCIA) to establish a fourth pathway for FDA drug approval for "biosimilar" drugs. But this pathway is available only if the brand biologic product is approved, or "licensed," under the Public Health Service (PHS) Act. Insulin products, including insulin glargine, have always been approved under the FDCA, not the PHS. So this pathway to approval has no applicability here. Nevertheless, biologics approved under the FDCA, like insulin glargine, enjoy the same efficiencies of approval under the § 505(b)(2) pathway as biosimilars do under the PHS. *See* § 7002(e) of the Affordable Care Act (ACA). So the § 505(b)(2) pathway, while largely used to obtain approval of small-molecule drugs, has been used on several occasions to obtain approval of biologics that are similar to the reference product and marketed as biosimilars in Europe.

~~pathway is available only if the brand biologic product is approved, or "licensed," under the Public Health Service (PHS) Act. Insulin products, including insulin glargine, have always been approved under the FDCA, not the PHS. So this pathway to approval has no applicability here. Nevertheless, biologics approved under the FDCA, like insulin glargine, enjoy the same efficiencies of approval under the § 505(b)(2) pathway as biosimilars do under the PHS.[7] So the § 505(b)(2) pathway, while largely used to obtain approval of small-molecule drugs, has been used on several occasions to obtain approval of biologics that are similar to the reference product and marketed as biosimilars in Europe.~~

2. The intersection of drug-approval laws and the patent laws.

a. Requirements for submitting patent information.

~~43.~~ ~~Section 505(b)(1) of the FDCA and FDA regulations require that a sponsor of an NDA submit to FDA a list of patents claiming either the approved drug substance or drug product, or an approved method of using the drug product described in the NDA.~~

(1) 1984: The text of the Act.

~~44~~45. ~~Specifically, § 505(b)(1) of the~~The Act requires NDA applicants to file, as part of the NDA,

> the patent number and the expiration date of any patent which claims *the drug* for which the applicant submitted the application or which claims a method of using *such drug* and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.[8]

46. But NDA holders cannot list just any patent in the Orange Book. The Act imposes two distinct limitations. NDA applicants may only submit patents for listing in the

[7] ~~See § 7002(e) of the Affordable Care Act (ACA).~~

[8] 21 U.S.C. § 355(b)(1) (~~emphasis added~~)all emphasis in this complaint added unless otherwise noted). The statutory language did not change during the time period relevant to this complaint.

Orange Book if they satisfy both criteria. First, the Act only permits applicants to seek to list patents that claim "the drug" or a method of using "the drug."[9] It does not, for example, condone listing patents that claims the drug packaging, or patents that claim the drug container. Second, of this defined universe of patents (those claiming "the drug" or a method of using "the drug"), the Act only permits applicants to submit the subset of patents that could "reasonably be asserted" against a would-be competitor. If the first criterion is not met then the patent must not be submitted for listing in the Orange Book. The inquiry ends there. Only if the first criterion is met is there any debate about whether the NDA holder could "reasonably" assert the patent against a theoretical competitor.

~~45. If an NDA applicant obtains additional patents that claim the drug or a method of using the drug after its NDA obtains approval, § 505(c)(2) requires the prompt submission of that patent information.[9]~~

~~46. The statutory language did not change during the time period relevant to this complaint.~~

47. If, after the FDA approves an NDA, an NDA holder obtains additional patents that claim "the drug" or a method of using "the drug," and if some of those patents could be reasonably asserted against a competitor, then the NDA holder must promptly submit that patent information for listing pursuant to § 505(c)(2).[10]

[9] As this case does not involve method of use claims, we focus here on the statute's

~~[9] 21 U.S.C. § 355(c)(2) (emphasis added) ("If the patent information described in subsection (b) of this section could not be filed with the submission of an application under subsection (b) of this section because the application was filed before the patent information was required under subsection (b) of this section or a patent was issued after the application was approved under such subsection, the holder of an approved application shall file with the Secretary the patent number and the expiration date of any patent *which claims the drug for which the application was submitted* or *which claims a method of using such drug* and with respect to which *a claim of patent infringement could reasonably be asserted* if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.").~~

[10] 21 U.S.C. § 355(c)(2) ("If the patent information described in subsection (b) of this section could not be filed with the submission of an application under subsection (b) of this section because the application was

48. NDA applicants are on their honor to properly identify the "[t]ype of patent, i.e., drug, drug product, or method of use."[11]

(2) 1994: The FDA's regulations and comments.

~~47~~49. In October 1994, the FDA issued final rules addressing the submission of patent information. The new rule, 21 CFR § 314.53, clarified that ~~a statutory language referring to~~ "[f]or purposes of this part," patents ~~"~~which claim~~s~~ the drug~~"~~ or ~~"~~a method of using ~~such~~the drug~~" are~~ "consist of drug substance (ingredient) patents, drug product (formulation and composition) patents, and method of use patents."~~[10] The~~[12]

50. In the regulation, the FDA admonished that "[f]or patents that claim a drug substance or drug product, the applicant shall submit information *only* on those patents that *claim a drug product* that is the subject of a pending or approved application, or that *claim a drug substance* that is a component of such a product." ~~And it admonished that, for method-of-use patents, "the applicant shall submit information only on those~~[13] The FDA's rule reiterated what had long been clear from the text of the Act: (1) only patents that claim ~~indications or other conditions of use of a pending or approved application."~~[11]the drug substance, a

filed before the patent information was required under subsection (b) of this section or a patent was issued after the application was approved under such subsection, the holder of an approved application shall file with the Secretary the patent number and the expiration date of any patent *which claims the drug for which the application was submitted* or *which claims a method of using such drug* and with respect to which *a claim of patent infringement could reasonably be asserted* if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.").

[11] 21 C.F.R. § 314.53(c)(2)(ii) (1999) & (2002).

~~[10] *Abbreviated New Drug Application Regulations: Patent and Exclusivity Provisions*, 59 Fed. Reg. 50338, 50344 (Oct. 3, 1994) (new and final rule publishing text of newly created § 314.53 – Submission of patent information and responding to comments re that section).~~

[12] *Abbreviated New Drug Application Regulations: Patent and Exclusivity Provisions*, 59 Fed. Reg. 50338, 50344 (Oct. 3, 1994) (new and final rule publishing text of newly created 21 CFR § 314.53 – Submission of patent information and responding to comments re that section) (quoting 21 CFR § 314.53).

[13] 21 C.F.R. § 314.53(b). The FDA also stated that, for method-of-use patents, "the applicant shall submit information only on those patents that claim indications or other conditions of use of a pending or approved application" (as opposed to other, unapproved, methods of use).

~~[11] *Id.*~~

formulation of the drug, or methods of using the drug, may be submitted for listing in the Orange Book, and (2) that, of that subset of patents, the NDA holder may only seek to list those that could be reasonably asserted against a competitor.

~~48~~51. The rule set forth the patent information a drug sponsor must provide, including "the type of patent, i.e., drug, drug product, or method of use" and the patent's expiration.[~~12~~14]

~~49~~52. The rule also required a specific declaration for formulation, composition, and/or method-of-use patents, stating: "The undersigned declares that Patent No._____ covers the formulation, composition, and/or method of use of *(name of drug product)*. This product is (currently approved under section 505 of the Federal Food, Drug, and Cosmetic Act) [or] (the subject of this application for which approval is being sought):~~-~~___~~.~~"[~~13~~15] The declaration had to be signed by "the applicant or patent owner, or the applicant's or patent owner's attorney, agent (representative) or other authorized official."[~~14~~16]

~~50~~53. During its rulemaking, the FDA considered and rejected ~~the~~an argument that the FDCA required NDA applicants to provide only patent numbers and patent expiration dates. The FDA explained that requiring additional patent information was consistent with the purposes of the Act, particularly in light of the FDA's lack of patent expertise:

> FDA does not have the resources or the expertise to review patent information for its accuracy and relevance to an NDA. Therefore, the agency declines the comment's requests to ensure that patent information is complete and relevant to an NDA and to confirm, upon request, the validity of patent information submitted to the agency. The agency believes that the declaration requirements under § 314.53(c), *as well as an applicant's potential liability if it submits an untrue statement of material fact*, will help ensure that accurate patent information is submitted.[~~15~~17]

[~~12~~14] *Id.* at § 314.53(c)(1).

[~~13~~15] *Id.* at § 314.53(c)(2)(i).

[~~14~~16] *Id.* at § 314.53(c)(4).

[~~15~~17] *Abbreviated New Drug Application Regulations: Patent and Exclusivity Provisions*, 59 Fed. Reg. 50338, 50345 (Oct. 3, 1994) (new and final rule).

~~51~~54. The FDA likewise considered and rejected a comment suggesting that there was no need to identify a patent according to whether it claimed drug substance, a formulation, composition, or method-of-use~~ that~~. That comment "suggested deleting the proposed rule's classification of patents and replacing it with a general certification that the patents listed by the applicant contain claims with respect to which the applicant could reasonably assert a claim of infringement . . . ." The FDA ~~concluded~~made clear that NDA applicants should *only* identify ~~which claims cover~~patents that claim the drug or drug product ~~and~~or which claims cover a method of use:

> *FDA acknowledges that a patent may contain a variety of claims*, and has revised proposed § 314.53(c)(2) by creating a single certification statement . . . . However, because section 505(b)(1) of the act specifically requires applicants to 'file with the application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application *or* which claims a method of using such drug,' and because FDA lacks patent law expertise, the agency strongly encourages applicants to identify, to the best of their ability, the type of patent covering the drug or drug product. This information will help FDA determine *which claims cover the drug or drug product and which claims cover a method of use.*~~16~~18

That is, the FDA's position was that an applicant *would not* comply with the requirements of the Act if it simply attested that the patents it asked the FDA to list could reasonably be asserted. The FDA reiterated the Act's first listing limitation and asked applicants to differentiate whether the patents it sought to list claimed "the drug or drug product" from those that covered methods of using the drug or drug product.

~~52~~55. Elsewhere in the commentary accompanying the amendment, the FDA stated:

> FDA does not have the expertise to review patent information. The agency believes that its scarce resources would be better

~~16~~18 *Id.* at 50343-44.

> utilized in reviewing applications rather than reviewing patent claims.[~~17~~19]
>
> The requirement in § 314.53(b) and (c) that applicants provide information on the type of patent … is consistent with the purpose of section 505(b)(1) of the act.[~~18~~20]
>
> The statute expressly requires applicants to file 'the patent number and the expiration date of any patent *which claims the drug* for which the applicant submitted the application . . .' (section 505(b)(1) of the act). Thus, if the formulation patent claimed the drug product in the application, the applicant must file information on that patent.[~~19~~21]

(3) 2003: The FDA's amendments and clarifications.

~~53~~56. On June 18, 2003, the FDA amended § 314.53 "to help ensure that NDA applicants submit only appropriate patents."[22]

57. The rules of the road did not change. The FDA kept the two distinct limitations as to which patents can be listed in the Orange Book, repeating the old language requiring applicants to submit "each patent that claims the drug or a method of using the drug that is the subject of the new drug application . . . *and* with respect to which a claim of patent infringement could reasonably be asserted [against a competitor]." The "reasonableness" inquiry still only came into play for patents that claim "the drug" or a method of using "the drug."

58. The FDA then added text addressing "patents for which information *must not* be submitted." Two additions are relevant here.

~~54. In short, the statute sets forth a two part test – the patent must both (i) claim "the drug . . . or . . . a method of using such drug", and (ii) be such that "a claim of patent~~

[~~17~~19] *Id.* at 50343.

[~~18~~20] *Id.* at 50343.

[~~19~~21] *Id.* at 50344.

[22] *Applications for FDA Approval to Market a New Drug: Patent Submission and Listing Requirements and Application of 30-Month Stays on Approval of Abbreviated New Drug Applications Certifying that a Patent Claiming a Drug is Invalid or Will Not Be Infringed*, 68 Fed. Reg. 36676-801 (June 18, 2003).

~~infringement could reasonably be asserted" against a proposed competitor product. NDA applicants are on their honor to properly identify the "[t]ype of patent, i.e., drug, drug product, or method of use."[20] And the patent's drug product claim could claim not just some drug product – it had to claim the relevant drug product, i.e., the FDA-approved drug product as to which the NDA applicant listed the patent.~~

59. First, the FDA confirmed that "[f]or patents that claim a drug product, the applicant shall submit information *only on those patents that claim a drug product, as defined in § 314.3*, that is described in the pending or approved application."[23] Section 314.3 stated, "[d]rug product is a finished dosage form, e.g., tablet, capsule, or solution, *that contains a drug substance* . . ." Section 314.3 defines "drug substance" as "an *active ingredient* that is intended to furnish pharmacological activity or other direct effect . . . ." Putting these three pieces together, the FDA's position was that – for patents that purportedly claimed a drug product – applicants shall submit information / request listing *only* for those patents that claim a finished dosage form that *contains the drug's active ingredient.*

60. The key language in 314.3 is "that contains the drug substance." This qualifier makes crystal clear that, for example, a patent claiming a new aspect of a tablet coating that does also claim a drug's active ingredient is not "a finished dosage form." As the canon of statutory and regulatory interpretation teaches, the phrase "that contains the drug substance" must be understood to have meaning. It cannot be presumed to be accidental or otherwise read out of the rule.

~~[20] 21 C.F.R. § 314.53(c)(2)(ii) (1999) & (2002).~~

[23] The patent's drug product claim cannot claim not just some drug product – it must claim the relevant drug product, i.e., the drug product that is the subject of the NDA in which the NDA applicant sought to list the patent.

61. Second, the FDA confirmed "[p]rocess patents, patents claiming packaging, patents claiming metabolites, and patents claiming intermediates must *not* be submitted for listing in the Orange Book."[24]

62. This additional exposition follows logically from the teachings of the Act and the earlier regulations. If a patent covered the drug's active ingredient (drug substance) and *also* packaging, it would satisfy the Act's first listing limitation, that it cover "the drug." And, if that patent could also be reasonably asserted against a competitor, it would satisfy the second limitation and must be listed in the Orange Book. But, if a patent covered only the packaging used in the drug product, and not the active ingredient, then it does not satisfy the first listing limitation and may not be listed in the Orange Book . . . and the second limitation as to "reasonably asserted" never comes into play.

63. In its responses to comments submitted on the proposed version of the 2003 regulations, the FDA further explained its prohibition on listing patents that covered packaging (and did not also claim the drug substance). The FDA noted that while "most comments agreed that patents claiming packaging should not be submitted for listing," some commenters argued that patents claiming "devices or containers," in particular metered dose inhalers, "should be submitted and listed" because they are "integral" to the drug product. In its response, the FDA began by acknowledging that patents claiming containers do not belong in the Orange Book:

> We agree that patents claiming a package or container must not be submitted. Such *packaging and containers are distinct from the drug product and thus fall outside of the requirements for patent submission.* However, we have clarified the rule to ensure that *if the patent claims the drug product as defined in § 314.3*, the patent must be submitted for listing.

[24] 21 C.F.R. § 314.53(b)(1).

64. The FDA then stressed that for a patent to claim a drug product, and for the NDA applicant to rely on that claim as the basis for being *potentially* eligible for listing in the Orange Book, the patent must claim a finished dosage form that contains the active ingredient/drug substance:

> Section 314.3 defines a "drug product" as "* * * a finished dosage form . . . *that contains a drug substance* . . . .

(Again, "drug substance" is defined as the active ingredient.[25])

65. The FDA noted that there is no ambiguity as to what the finished dosage form of a particular drug is:

> The appendix in the Orange Book lists current dosage forms for approved drug products. The list includes metered aerosols, capsules, metered sprays, gels, and pre-filled drug delivery systems.[26]

66. The FDA then concluded that the relevant question is *not* whether the patent covers *an aspect of* the finished product, but rather whether it claims the drug substance/active ingredient:

> The key factor is whether the patent being submitted claims the finished dosage form of the approved drug product. Patents must not be submitted for bottles or containers and other packaging, as these are not "dosage forms."

67. In summary, as applicable here, the Act sets forth a two-part test for determining whether a patent should be submitted to the FDA for listing in the Orange Book.

68. First, the patent must claim "the drug . . . or . . . a method of using such drug." And whether a patent claims "the drug" turns on whether the patent claims a finished dosage form *that contains the active ingredient.* This initial inquiry is binary. The patent either does or

[25] 21 CFR § 314.3.

[26] Appendix C to the Orange Book lists "dosage forms" approved by the FDA. At all times relevant, "injectable" was a dosage form. So was "system." Relatively few approved drug products are identified as a "system." In the current version of the Orange Book, there are four products described as a "system" dosage form.

does not claim a finished dosage form that contains the active ingredient under an objective standard.

69. Second, if and only if the first criteria is satisfied, the patent must be one that "could reasonably be asserted" against a proposed competitor product. The "reasonableness" standard only applies to the second half of the test: whether a claim of infringement could be asserted.

70. So when it comes to determining the propriety of listing a patent under the auspices that it claims the drug product, the relevant question is *not* whether the approved drug product includes a container protected by a patent. The correct question is whether the patent to be listed claims the drug substance as well as the container. If it does (again, a binary and objective determination), and if it could be reasonably asserted against a competitor, then the NDA application must provide information and ask the FDA to list the patent in the Orange Book. If the patent claims only a container or packaging, and *not* the active ingredient, then the regulations prohibit NDA applicants from asking the FDA to list patent.

b. Requirements for patent certifications.

~~55. A drug product with an effective approval under section 505(c) of the FDCA is known as a *listed drug*.~~

~~56~~71. As described above, the FDCA permits submission of § 505(b)(2) or § 505(j) applications for follow-on or generic versions of ~~listed~~already approved drugs. Both processes shorten the time and effort needed for approval by, among other things, allowing applicants to rely on the FDA's previous finding of safety and effectiveness ~~for a listed drug~~. Each applicant must identify the ~~listed~~approved drug on which it seeks to rely for approval.

~~57~~72. The timing of § 505(b)(2) and ANDA approvals depends on, among other things, the intellectual property protections for the listed drug that the § 505(b)(2) or ANDA application references~~,~~ and whether the applicant challenges those protections.[21] ~~In general, a would-be competitor who has submitted a § 505(b) application or ANDA may not obtain final approval until listed patents and any marketing exclusivity have expired or until NDA holders and patent owners have had the opportunity to defend relevant patent rights in court.~~[27]

~~58~~73. ~~With respect to~~For each patent ~~submitted by the sponsor for the listed drug and~~ listed in the Orange Book, a § 505(b)(2) applicant generally must ~~submit to FDA~~make one of four ~~specified~~ certifications under ~~section~~ § 505(b)(2)(A) of the ~~FCA. The certification must state one of the following.~~FDCA:

> (I) That the required patent information relating to such patent has not been filed, e.g., that there are no patents listed in the Orange Book (paragraph I certification).
>
> (II) That such patent has expired (paragraph II certification).
>
> (III) That the patent will expire on a particular date, and the applicant will not sell its competing product before that date (paragraph III certification).
>
> (IV) That such patent is invalid or will not be infringed by the drug for which approval is being sought (paragraph IV certification).

~~59~~74. The purpose of these certifications is "to give notice, if necessary, to the patent holder so that any legal disputes regarding the scope of the patent and the possibility of

[21] ~~*See* FDCA §§ 505(b)(2), (c), (j)(2)(A)(vii), and (j)(5)(B). Relevant intellectual property protections affecting the timing of ANDA approval include marketing exclusivity and listed patent protection for the listed drug.~~

~~Marketing exclusivity is not at issue here.~~

[27] *See* FDCA §§ 505(b)(2), (c), (j)(2)(A)(vii), and (j)(5)(B). Relevant intellectual property protections affecting the timing of ANDA approval include marketing exclusivity and listed patent protection for the listed drug.

infringement can be resolved as quickly as possible."[22][28] The certification is made to the FDA and to the company that holds the NDA for the already approved product.

60[75]. If an applicant files a paragraph I or II certification, the[no] patent in question will not delay application approval. If an applicant files a paragraph III certification, the applicant agrees to wait until the relevant patent has expired before seeking full effective approval of its application.

61[76]. If the patent has not expired, but the applicant believes its product does not infringe any valid listed patent, a paragraph IV certification may be filed as to substance or formulation patents. (Method-of-use claims have an alternative, optional special proceduresprocedure not relevant here).

c. Paragraph IV litigation and 30-month stays.

62[77]. As described, a § 505(b)(2) applicant may seek FDA approval before expiry of all Orange Book listed patents by filing a paragraph IV certification stating that a listed patent "is invalid or will not be infringed by the manufacturer, use, or sale of the [applicant's] drug."[23][29]

63[78]. The applicant filing a paragraph IV certification must also provide notice to the NDA holder and the patent owner stating that he has submitted an ANDA with a paragraph IV certification and[,] explaining the factual and legal bases for the applicant's opinion that the patent is invalid or not infringed.[24][30]

64[79]. Filing an ANDA or § 505(b)(2) application containing a paragraph IV certification provokesmay provoke litigation. The patent statute treats such filing as an act of

[22][28] *Torpharm, Inc. v. Thompson*, 260 F. Supp. 2d 69, 71 (D.D.C. 2003).

[23][29] 21 U.S.C. § 355(b)(2).

[24][30] *See* FDCA §§ 505(b)(2)(B) & (j)(2)(B).

technical infringement and provides the brand company an opportunity to sue.[25] If the patent owner or NDA holder brings a patent infringement suit against the § 505(b)(2) applicant within 45 days of the date it received notice of the paragraph IV certification, the approval of the § 505(b)(2) application will automatically be stayed for 30 months, or less if the patent litigation is resolved sooner.[26] When the 30 months have expired, the patent ceases to be a barrier to final FDA approval, even if the patent litigation is ongoing. Similarly, if the NDA holder and patent owner receive notice of a paragraph IV certification and do not sue within 45 days of receipt of notice, the patent will not be a barrier to FDA final approval.[31]

6580. If the branded drug manufacturer initiates a patent infringement action against its would-be competitor within forty-five days of receiving notification of the paragraph IV certification, the FDA will not grant final approval to the ANDA until the earlier of (a) the passage of 30 months, or (b) the issuance of a decision by a court that the patent is invalid or not infringed by the § 505(b)(2) applicant's product.

66. 81. Until one of those conditions occurs, the FDA may grant "tentative approval" but cannot grant "final approval" which would authorize the § 505(b)(2) applicant to market its product. The FDA may grant a § 505(b)(2) application tentative approval when it determines that the application would otherwise be ready for final approval were it not for the regulatory 30-month stay. Tentative approval is granted only when the applicant satisfies all scientific and procedural preconditions to final approval.[27][32]

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[25] *See* 35 U.S.C. § 271(e)(2)(A).

[26] *See* FDCA §§ 505(c)(3)(C) & (j)(5)(B)(iii).

[31] *See* 35 U.S.C. § 271(e)(2)(A).

[27][32] *Ranbaxy Labs. Ltd. v. FDA*, 307 F. Supp. 2d 15, 19-21 (D.D.C. 2004) ("Approvals do not become effective by operation of law because the FDA has an ongoing health and safety responsibility to perform."); 21 U.S.C. § 355(j)(5)(B)(iv)(II)(dd)(BB) ("A drug that is granted tentative approval by the Secretary is not an approved drug and shall not have an effective approval until the Secretary issues an approval after any necessary additional review of the application."); 21 C.F.R. § 314.107(b)(3)(v) ("Tentative approval of an application does not

~~67~~82. At bottom: under the procedures established in the Hatch-Waxman Amendments, a § 505(b)(2) application will not be approved until all listed patents: (1) have expired; (2) have been subject to a paragraph IV certification pursuant to which the patent owner or NDA holder has declined to sue within 45 days~~, or~~; (3) have been subject to a paragraph IV certification that led to a lawsuit and either (i) a decision favorable to the applicant was reached, or (ii) the automatic 30-month stay that issued upon the filing of suit has expired.

d. 2005-2012: Brand company submissions to the FDA confirmed that patents covering *only* a drug delivery device cannot be listed.

83. The proper interpretation of the drug regulations, including the Orange Book listing provisions, is not dictated by brand drug companies. Instead, the FDA is charged with interpreting the FDCA, the Hatch-Waxman Amendments, and subsequent amendments; promulgating regulations consistent with that interpretation; and interpreting and enforcing those regulations. Courts owe the FDA's interpretations of the law (not the brand company's arguments) substantial deference, and the FDA's interpretations of its own regulations absolute deference.[33]

84. The FDA provides multiple channels through which brand companies, generic companies, or the public can comment on its regulations and interpretations. Anyone can petition the FDA to "issue, amend, or revoke a regulation or order, or to take or refrain from taking any other form of administrative actions."[34] Two types of petitioning are relevant here.

constitute 'approval' under FDCA ~~"~~and cannot, absent a final approval letter from the agency, result in an effective approval").

[33] *See Chevron, U.S.A., Inc. v. Nat'l Resources Defense Council, Inc.*, 467 U.S. 837 (1984) (requiring courts to defer to any reasonable interpretation by an administrative agency of its enabling statute); *Bowles v. Seminole Rock & Sand Co.*, 325 U.S. 410 (1945) (holding an agency's interpretation of its own regulation is entitled to "controlling weight" unless "plainly erroneous or inconsistent with the regulation").

[34] 21 C.F.R. 10.25(a).

First, so-called "citizen petitions" directed at requesting changes specifically applicable to one drug, or class of drugs, may be filed pursuant to 21 C.F.R. § 10.30. Second, requests for advisory opinions seeking answers to a question of general applicability may be filed pursuant to 21 C.F.R. § 10.85.

85. For many years, brand drug companies often exploited the citizen petition route as a tool for (unlawfully) thwarting competition. The pharmaceutical industry knew that it was the FDA's practice to delay approving an application for a would-be competing product until it had resolved all citizen petitions addressing those applications. Many companies submitted citizen petitions that explicitly asked the FDA *not to approve applications for competing drugs* unless/until it had made the changes requested in the citizen petition; many of those petitions did not provide a reasoned basis for changing the existing rules. In 2006, Gary Buehler, then the head of the Office of Generic Drugs at the FDA, noted that of 42 citizen petitions raising issues about the approvability of generic products, "very few" – in fact, just three out of forty-two – "presented data or analysis that significantly altered FDA's policies."[35]

86. Both citizen petitions and requests for advisory opinions are opportunities to advocate for what a stakeholder *wishes* the drug laws and regulations permitted or required, in contrast to what the drug laws and regulations *actually* require.

87. From 2005 to 2012, brand drug companies submitted five letters ostensibly requesting advisory opinions, all addressing patents that claim packaging used in approved drug products.

[35] In 2007, Congress amended the drug laws to try to prevent this. But that has not stopped some companies' efforts at delay. In 2017, Scott Gottlieb, the Commissioner of Food and Drugs, told Congress that many of petitions are "intended primarily to delay the approval of competing drug products" rather than to raise "valid scientific or public health issues." "They merely "diverted resources" and "introduce[d] an unneeded and unhelpful inefficiency and cost." *Antitrust Concerns and the FDA Approval Process*, Statement of Scott Gottlieb, M.D., Comm'r of Food & Drugs before the House Committee on the Judiciary, Subcommittee on Regulatory Reform, Commercial and Antitrust Law (Jul, 27, 2017).

88. At the time, there was no industry confusion as to whether non-drug patents could be submitted for listing in the Orange Book. All five letters acknowledge that the statute, regulations, and the FDA's interpretation of its regulations only permit NDA holders to submit patents for listing that claim the finished drug form *and the drug substance/active ingredients.* None proffer an interpretation of the existing rules that permits listing patents that claim packaging *without* claiming the drug substance. Rather, all state that the FDA "should" change its rules to permit listing patents that *do not* claim the drug substance; none argue that they are entitled to list such patents under the existing framework. None provide even a reasoned basis or evidence that would permit the FDA to make such a change. And none disclose their author's most likely motivation: to leverage non-drug patents into the statutory thirty-month stay associated with Orange Book listed patents.

89. The faux requests for advice belie what these drug companies *actually* knew about the FDA's regulations and clarifications. Some companies, like GlaxoSmithKline ("GSK") and Novo Nordisk, had held patents covering an aspect of their drugs' packaging for years and had not submitted *those patents for listing in the Orange Book*. Other companies, like AstraZeneca and Forest, admitted that the regulations did not permit them to list these patents and, in the next breath, stated that they were submitting these patents for listing anyway: effectively, they admitted they were violating the law.

(1) 2005: GSK asks the FDA to change its regulations so that it can list in the Orange Book patents covering its Flonase packaging.

90. GSK submitted the first letter requesting an advisory opinion in 2005, hoping to change the FDA's position so that it could erect a further patent roadblock to follow-on competition to its blockbuster product, Flonase.[36]

[36] *See* Petition, Docket No. FDA-2005-A-0476 (Jan.10, 2005).

91. It is important to put GSK's request in context. At that time, GSK was facing imminent generic competition to its blockbuster drug Flonase. GSK was desperate to prolong its monopoly for its biggest moneymaker. So GSK sought to exploit the FDA's and Congress's patent listing requirements in order to eke out every last dollar that it could from branded prescription Flonase.

92. GSK had already filed multiple citizen petitions asking the FDA, explicitly, to "refrain from approving ANDAs" seeking to manufacture and sell generic Flonase unless the would-be competitors performed additional, onerous laboratory testing that the FDCA itself said was unnecessary. The petitions were meritless, but successfully delayed competition. GSK eventually paid about $200 million to resolve antitrust suits (including one brought by a delayed competitor) claiming that its citizen petitions were anticompetitive and delayed generic competition for Flonase.[37]

93. If it thought it had a basis to list its packaging patents in the Orange Book, and that it could launch a non-sham lawsuit over those patents, it would have.

94. GSK's letter addressing patent listing requirements admitted that the FDA does not permit brand drug companies to submit Orange Book listings for patents that do not claim active ingredients, but argued that the FDA should *change* that policy.

95. First, GSK described the existing statute and regulations. It admitted that § 505(b)(1) limits brand drug companies to listing only a "patent which claims the drug for which the applicant submitted [an NDA] or which claims a method of using such drug . . . ."[38] It described the 2003 amendments to the Orange Book listing regulations, and conceded that those regulations limited Orange Book listings to only those patents that

[37] *See generally In re Flonase Antitrust Litig.*, No. 08-cv-3301 (E.D. Pa.).

claim the "finished dosage form."[39] And although it claimed the FDA allowed for the listing of patents covering some delivery devices, it conceded this narrow exception was limited to circumstances where the patent claimed the actual drug substance *and* the packaging.[40]

96. Using nasal aerosols (like Flonase) as an example, GSK cited the FDA's reasoning:

> Nasal aerosols usually consist of the formulation, container, valve, actuator, dust cap, associated accessories, and protective packaging, ***which together constitute the drug product***.
>
> Similarly, nasal sprays usually consist of the formulation, container, pump, actuator, protection cap, and protective packaging, ***which together constitute the drug product***. (emphasis in the original)[41]

97. In other words, GSK knew that the FDA allowed brand companies to submit patents for listing in the Orange Book if the patent claimed the formulation *and* portions of packaging integral to using the formulation.

98. Second, GSK asked the FDA to change its current practice. It asked the FDA to *expand* that rule, to allow brand companies to list:

> patents that . . . do not *claim* the drug substance generally (as in 'medicament') or by class (as in 'antiinflamatories' or 'bronchodialators') or specifically (as in 'albuterol' or 'terbutaline') or by chemical name (as in '9-chloro-11β,17, 21-trihydroxy-16β-methylpregna-1,4,diene-3,20-dione-17,21-diporpionate') in conjunction with the delivery device . . . .

and patents that "otherwise do not reference the drug substance in any manner in the patent, such that the topic, theme, or premise of the patent is directed to the device itself."[42]

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[38] *Id.* at 2 (citing 21 U.S.C. § 355(b)(1).

[39] *Id.* at 2-3.

[40] *Id.* at 3-4 (nothing that, additionally, the packaging must be somehow "integral" to the use of the drug product).

[41] *Id.* at 3 (quoting *Draft Guidance for Industry: Bioavailability and Bioequivalence Studies for Nasal Aerosols and Nasal Sprays for Local Action* (Apr. 2003) at lines 208-11) (emphasis GSK's); *see also id.* at 4 (citing similar FDA language about metered dose inhalers).

99. GSK could not point to anything in the statute, regulations, or FDA's actions that suggested that the current law permitted (however unclearly), the listing of patents that do not claim the actual drug substance itself. It argued only that, in its view, such listings should be permitted to provide generic companies with "notice" that the brand company might sue.[43]

100. But GSK neglected to mention the other important function of the Orange Book listing: to enable to brand companies to automatically delay competition by asserting a listed patent. GSK only acknowledged that, if listed, non-drug patents that claimed some portion of the drug's patenting "would then be the subject of prompt (premarket) certifications and possibly patent infringement litigations, as authorized under the Hatch Waxman Amendments . . . ."[44]

101. GSK's oblique reference to "premarket" suits is telling. GSK was not suggesting that, unless it could list non-drug patents in the Orange Book, it could not assert its intellectual property rights: it effectively conceded that it had a right to "[post]marketing" enforcement of patents claiming items other than the drug substance or formulation (just like every other patentee of a non-drug invention). Instead, it hoped to avail itself of the version of infringement litigation that was "authorized under the Hatch-Waxman Amendments" – i.e., the version of infringement litigation that automatically delayed competition.

102. Lest there be any doubt that GSK *knew* the current version of the FDA's laws and regulations *did not* allow listing of patents that "do not *claim* the drug substance generally . . . or by class . . . or specifically . . . or by chemical name," or patents that "otherwise do not reference the drug substance," the final section of its petition resolved all doubt. GSK told the

[42] *Id.* at 4-5.

[43] *Id.* at 6-7.

[44] *Id.* at 6.

FDA it "has *not* listed patents that do not claim the approved drug substance either generally or specifically," nor patents "covering protective packaging . . . ."[45]

103. On July 7, 2005, the FDA issued a tentative response to GSK's petition, stating that it "ha[d] been unable to reach a decision on [GSK's] request due to the need to address other Agency priorities."[46] The FDA's response, required by law to be sent within six months of a petition filing, did not mean it had determined that listing non-drug patents in the Orange Book was proper; nor that it was puzzling through the petition. It simply meant the FDA had not yet answered the petition because other matters were more pressing.

(2) 2006: AstraZeneca echoes GSK's request for a change in the Orange Book listing regulations.

104. On August 10, 2006, AstraZeneca (through its lawyers) filed its own petition, asking the FDA to change its regulations. At the time, AstraZeneca had a number of blockbuster respiratory products in proprietary inhalers and devices – such as Advair, Pulmicort, and Symbicort, that would soon face the prospect of competition when their drug substance patents expired. AstraZeneca acknowledged that the final regulations limited brand companies to listing only patents that "claim[] the finished dosage form of the approved drug product." And it acknowledged that "patents directed to drug delivery systems . . . that do not recite the approved active ingredient or formulation" were *not* included in this category.[47]

105. AstraZeneca argued that it believed "that the requirement for listing drug products that are finished dosage forms, such as [metered dose inhalers], *should* encompass

[45] *Id.* at 7.

[46] Interim Response Letter, Docket No. FDA-2005-A-0476 Jul. 7, 2005). This tentative response – and those sent to the later petitioners – were required to be sent by statutes and regulations requiring the FDA to send a letter within 6 months of receiving the petitions. They did not reflect anything about the FDA's thinking on the issues raised, and certainly did not imply that the petitioners' requests were reasonable in the FDA's view. *See* 21 CFR 10.30(e)(2).

[47] *See* Petition at 1-2, Docket No. FDA-2006-A-0063 (Aug.10, 2006).

patents directed to the inhalation device of the approved drug product, even if the formulation or active ingredient is not specifically mentioned or claimed in the patents."[48] AstraZeneca claimed that listing these non-drug patents in the Orange Book would further the Hatch-Waxman Amendments' goal "to provide generic manufacturers with notice of the patents that would be infringed . . . and to permit early resolution of challenges to patents before marketing begins." But AstraZeneca, like GSK before it, demurred on the true objective: triggering automatic thirty-month stays of approval for follow-on products. AstraZeneca wrote that listing the patents in the Orange Book would entitled generic manufacturers to "a 180-day exclusivity period for successful challenges to the validity, enforceability or infringement" of the listed non-drug patents. But a generic competitor can enjoy that 180 days only after waiting out the thirty-month stay.[49]

106. AstraZeneca told the FDA it was already listing such patents in the Orange Book, and would "continue to list them unless it receives guidance from FDA that such listings are improper."[50]

107. On February 2, 2007, the FDA sent a tentative response letter, saying that it had not "reach[ed] a decision on [AstraZeneca's] request due to the need to address other Agency priorities."[51]

(3) 2007: AstraZeneca tries again.

108. On June 21, 2007, AstraZeneca (through its lawyers) again tried to influence the FDA to change its regulations to allow listing of non-drug patents in the Orange Book with a

[48] *Id.* at 2.

[49] *Id.* at 2.

[50] *Id.* at 3.

[51] *See* Interim Response, Docket No. FDA-2005-A-0476 (Feb. 2, 2007).

second petition. Again, it acknowledged that the regulations did not currently permit the listing of non-drug patents, noting the "FDA ha[d] not directly addressed the question whether the listing requirement applies to patents for approved drug delivery systems where the patents disclose bit do not claim, or neither disclose nor claim, the active ingredient or formulation of the approved drug product." It then reiterated its normative arguments about why it should be allowed to list non-drug patents in the Orange Book.[52]

109. On December 17, 2007, the FDA issued a tentative response, again informing AstraZeneca that it was focusing on "other Agency priorities."[53]

(4) 2009: GSK changes its practice to list patents it previously admitted it knew were not listable.

110. On February 11, 2009 – four years after it admitted it did not think non-drug patents were listed in the Orange Book – GSK supplemented its 2005 petition, informing the FDA that it had decided to "modif[y] its Orange Book listing practice" to list non-drug patents "including those patents that claim all or a portion of integrated drug-device products, regardless of whether the approved drug substance is specifically mentioned in the claims of such patents."[54] GSK did not put forward – here or anywhere – an interpretation of the statute or regulations that permitted it to do so. It simply announced that it was defying the rules.

(5) 2009: Forrest asks the FDA to change its regulations to allow listing of non-drug patents.

111. On May 12, 2011, Forrest Laboratories, Inc., though its lawyers, joined the fray. At the time, Forest apparently sold Aerobid, a metered-dose inhaler (since discontinued). Like GSK and AstraZeneca, Forrest took the position that "neither the rules nor past guidance from

[52] *See* Petition, Docket No. FDA-2007-A-0099 (June 21, 2007).

[53] *See* Interim Response, Docket No. FDA-2007-A-0099 (Dec. 17, 2007).

[54] *See* Suppl. Petition, Docket No. FDA-2005-A-0476 (Feb. 11, 2009).

the FDA address" whether "current FDA accepted practice regarding listing of drug delivery device patents require submission for listing in the Orange Book of" patents that "claim[] a drug delivery device" but "do[] not recite the active ingredient."[55]

112. Forrest, like the other companies, did not point to anything in the existing regulations that even suggested that patents *not* claiming the active ingredient *could* be listed. It just argued that it "should" be allowed to list non-drug patents, "irrespective of whether the patent recites the active ingredient in the claims."[56]

113. Forrest, like the others, glossed over the fact that listing non-drug patents in the Orange Book would enable brand companies to delay follow-on competition. Instead, Forrest argued that erecting these additional barriers to follow-on competition actually "benefit[s]" the "generic drug manufacturer."[57]

114. Forrest told the FDA it would "continue to list" its non-drug patents in the Orange Book because the FDA had not yet answered the prior three petitions, and because "the FDA accepts the submissions of such patents and later lists them in the Orange Book." Forrest said what is usually unspoken: it would submit these patents for listing – irrespective of whether the current rules permitted it to do so – because it knew the FDA had no choice but to list them. (But recall, the FDA's role in listing patents in the Orange Book is merely "ministerial" – so Forrest should not have inferred anything from that fact.)

115. On November 7, 2011, the FDA sent a tentative response letter, indicating it had not yet answered Forrest's petition because of "the need to address other Agency priorities."[58]

(6) 2012: Novo Nordisk acknowledges that it had no basis to list non-drug patents in the Orange Book.

[55] *See* Petition, Docket No. FDA-2011-A-0363 (May 12, 2011).

[56] *Id.* at 3.

[57] *Id.* at 4.

[58] *See* Interim Response, Docket No. FDA-2011-A-0363 (Nov. 11, 2011).

116. On November 26, 2012, Novo Nordisk filed a petition with the FDA.[59] It listed a number of its products which had been on the market for years – including diabetes products – available in "pre-filled pen-injector presentations (FlexPen® or FlexPro®)" and "a pre-filled Penfill® cartridge for a Penfill® cartridge device." It admitted that although the pen-injectors and cartridges "are covered by several issued patents, Novo Nordisk has not previously submitted information to FDA on those patents for listing in the Orange Book."[60]

117. Novo Nordisk admitted that the existing regulations and FDA statements did not explicitly permit the listing of these non-drug patents, and that the FDA "ha[d] not . . . publicly addressed the patent listing issues" regarding the listing of non-drug patents in the Orange Book. It admitted that brand companies could submit for listing only those patents that "claim[] the finished dosage form of the approved drug product." And it admitted that the relevant "dosage forms" are those uniform terms listed in Appendix C of the Orange Book.[61]

118. By this time, in 2012, Novo Nordisk surely had no reasonable expectation that the FDA would provide an answer on the listing of non-drug patents. First, as described above, the FDA does not adjudicate the propriety of listing a particular patent in the Orange Book: it counts on the brand companies to be truthful, and performs only a ministerial task in listing the submitted patents. Second, the FDA had four times stated that it had not yet addressed the issue, because it had other regulatory priorities. Third, the FDA's interpretation of its congressional mandate was clear and reasonable, both from the original rules (1994) and its clarifications (2003); there was no need for the FDA to say more.

119. Predictably, on May 23, 2013, the FDA advised that it had not yet resolved Novo Nordisk's inquiry, "due to the need to address other Agency priorities."[62]

[59] *See* Petition, Docket No. FDA-2012-A-1169 (Nov. 26, 2012).

[60] *Id.* at 1-2.

[61] *Id.* at 3-4.

(7) The FDA never granted or endorsed any of these brand companies' self-serving requests.

120. There was no confusion in the drug industry as to what types of product patents could be properly submitted for listing in the Orange Book. Every one of the aforementioned petitions admitted that the current law and regulations did not allow listing a patent claiming an aspect of a product's packaging unless the patent also claimed the active ingredient. And the regulations were clear that the onus in determining whether a patent satisfied the listing requirements fell on the NDA holder, not the FDA. The only inference to be drawn from these petitions, which offered only normative arguments for *changing* the law, is that these brand companies sought (unsuccessfully) to have the FDA sanction a new means for them to delay competition.

121. The fact that the brand industry wanted to erect additional roadblocks to competition does not mean that those roadblocks existed. Nor does the fact that multiple brand-namecompanies wanted the same anticompetitive result mean that their intent or request was reasonable.

122. The speed limit on the Massachusetts Turnpike is 65 miles per hour. The fact that everyone drives 77 mph does not change the law. Nor will an argument that the speed limit *should* be 77 miles per hour (because you want to get home sooner) get you out of a ticket. Maybe you have even petitioned the legislature to change the speed limit from 65 mph to 77 mph; you're still getting a ticket. You don't get out of it just because the State House hasn't responded to your request. There are many reasons they might not act on your petition – lack of time, lack of resources, the fact that raising the speed limit is a terrible idea – but none of

[62] *See* Interim Response, Docket No. FDA-2012-A-1169 (May 23, 2013).

those reasons raise the inference that your petition stakes out a correct or reasonable interpretation of the existing 65 mph speed limit.

123. The FDA is a resource- and time-constrained agency. There are competing demands on its time. Generally, it focuses on its charter: enhancing the public health by encouraging, rather than frustrating, the availability of affordable versions of very expensive, critical, drugs like Lantus.

124. When it takes time to implement rules or clarify its rules, it is unlikely to spend additional resources responding to requests squarely governed by existing rules, or requests that those rules be changed when the petitioner provides no compelling basis for the FDA to do so. This is particularly true in an area like patent listing, where the FDA's role is ministerial; the agency lacks patent-law expertise or resources to evaluate patents; and the agency has made clear that the onus is on *applicants* to do it right.

125. The FDA's silence here – despite the repeated petitions from brand-name companies – is deafening.

e. Brand name drug companies can enforce patents that are not listed in the Orange Book.

126. For years before the Hatch-Waxman Amendments became law, there was no centralized source from which would-be competitors could determine which patents a brand company thought protected its drug product, formulation, or method of using the drug product. Competitors bore the responsibility of identifying patents held by others that their own competing products may infringe and either designing around those patents, negotiating licenses for those patents, or – when it concluded the arguably applicable patents were invalid or unenforceable – choosing to launch a product knowing that it may ultimately have to defend itself in an infringement suit. Under this earlier scheme, a patent-holder could not sue until the

competitor actually launched a product; if the patent-holder's suit were successful – if it proved infringement – the competitor would have to pay the brand damages based on its actual sales.

127. This was how drug companies defended their intellectual property for many years: by suing competitors who had already launched products that the brand believed infringed. (This, by the way, is how patent holders still defend their intellectual property in all other fields.)

128. The Hatch-Waxman Amendments changed things, but only for specific types of patents: patents covering the finished drug product, drug formulations/ compositions of the finished drug product, and methods of using the finished drug product.[63] For those kinds of patents, and only those, Congress created a tradeoff: competitors benefit from (1) a central list of patents that covered the most elemental aspects of a drug (the active pharmaceutical ingredient in the drug, its dosage form, and how the drug is used) and (2) a truncated application process.[64] Brands benefit from (1) being able to bring infringement suits asserting product, formulation, and method of use claims *before* a generic product launched, once a competitor had filed an application, and (2) having two-and-a-half years to resolve those infringement claims before the FDA would approve the ANDA or § 505(b)(2) application. The result of this trade off, according to one commentator, is that "Orange Book listing elevates every patent as a potential source of delay to generic competition," because listing gives "the patentee/NDA holder almost automatic injunctive relief for even marginal infringement claims."[65]

[63] 21 USC 355 (b)(1).

[64] Competitors that file an ANDA also receive an additional benefit: the opportunity to enjoy 180 days free from competition if they are the first applicant to file an ANDA containing a paragraph IV certification. This benefit does not come into play in this case.

[65] Terry G. Mahn, Patenting Drug Products: Anticipating Hatch-Waxman Issues During the Claims Drafting Process, 54 Food Drug L.J. 245, 250 (1999) (quoted in *Andrx Pharmaceuticals, Inc. v. Biovail Corp.*, 276 F.3d 1368, 1378 n.6).

129. But this tradeoff did not apply to *all* patents that protect prescription drugs. Drug companies may also have patents that protect the process by which it makes the drug; patents that cover a metabolite made when a person ingests the drug; patents that cover intermediate forms of the active ingredient; and patents that cover pharmaceutical packaging or containers. Federal regulations confirm that these types of patents *must not* be listed in the Orange Book.[66] Because they are not listed in the Orange Book, they cannot trigger an automatic two-and-a-half-year delay in approval and so do not prevent others from launching competing products.

130. That said, drug companies can and do enforce patents that are not listed in the Orange Book.[67] The default patent enforcement mechanism applies: once a competitor launches, but not before, the patent holder can sue for infringement of the unlisted patent – if it has a realistic expectation of succeeding in proving the competitor infringed a valid patent. The patent holder can then try to obtain an injunction requiring the competitor to take its product off the market, but faces a very high burden in establishing its likelihood of ultimate success in proving infringement. If the patent holder ultimately prevails on the merits, it can obtain damages for the infringing sales.

131. Courts are quick to nip in the bud efforts to assert unlisted patents *before* the competing product actually launches. For example, in 2003, during Hatch Waxman litigation involving other (listed) patents, Pfizer sought to amend its pleadings to add allegations that Ranbaxy intended to infringe two unlisted process patents. Ranbaxy opposed Pfizer's efforts.[68]

[66] 21 CFR 314.53(1) (listing "[p]rocess patents, patents claiming packaging, patents claiming metabolites, and patents claiming intermediates").

[67] For example, AstraZeneca unsuccessfully tried to sue over patents it contended claimed its blockbuster drug Nexium, but which were not listed in the Orange Book, before its would-be competitors launched the product. As described below, GSK did the same as to Lipitor.

[68] Ranbaxy also vigorously challenged the substance of Pfizer's infringement allegations as to these process patents.

The Court concluded that Pfizer lacked standing to assert the process patents; that Pfizer's attempt to join claims for infringing the process patents were "premature"; and that "waiting for any claims involving Ranbaxy's manufacturing process to mature" would not prejudice Pfizer "in any way."[69]

f. Would-be competitor drug companies can challenge brand-name patents in front of the PTO.

132. Since the 1980s, Congress has provided a patent reexamination system for third parties to challenge the validity of patents. Under the 2011 Leahy-Smith America Invents Act,[70] reexamination proceedings evolved into the *inter partes* review system (IPR) for challenging patent validity.

133. Under the IPR system a group of Administrative Law Judges of the Patent Trial and Appeals Board ("PTAB") adjudicates a proceeding that resembles a litigation, complete with the filing of petitions and responses similar to motion practice, some discovery, and a hearing.[71]

134. Anyone may petition the patent office to review the enforceability of a patent.[72]

135. The PTAB may institute review if it finds that "the petition supporting the ground would demonstrate that there is a reasonable likelihood that at least one of the claims

[69] *Pfizer Inc. v. Ranbaxy Laboratories Ltd.*, 03-cv-209 (D. Del. 2003) (ECF No. 139) (summarized in *Pfizer Inc. v. Ranbaxy Labs Ltd.*, 08-cv-164 (D. Del. May 1, 2008) (ECF No. 10)).

[70] P.L. 112-29, 125 Stat. 284 (2011).

[71] *See generally* 37 C.F.R. §§ 42.20-25, 42.51-65, 42.70, 42.73.

[72] 37 C.F.R. § 42.101. *See also* Office Patent Trial Practice Guide, 77 F.R. 48756-01 (August 14, 2012). Persons are only disqualified from bringing an IRP for reasons other than their rights, for example, if a party has already instituted a court action seeking a declaratory judgment of invalidity, they cannot petition for PTAB review. America Invents Act § 315(a)(1).

challenged in the petition is unpatentable."[73] Then, parties may request additional discovery.[74] The Board may then make a decision on whether or not to institute a trial, where it decides the validity of a patent based upon a preponderance of the evidence.[75]

136. This process frequently reveals that the patents challenged are invalid. Since the PTAB began accepting petitions on September 16, 2012, there have been a total of 7,685 petitions filed. Of those, 1,817 ended with Final Written Decisions, of those decisions, 65% had all claims deemed unpatentable and an additional 16% had some claims deemed unpatentable.[76]

B. The effect of follow-on biologics or generic drugs on competition.

137. Once a brand drug company's lawful exclusivity over its patented drug runs out and it faces competition from less-expensive competitors, expensive brand sales fall rapidly as the market shifts toward the competitor products.

138. But as a Rand Corporation study cautioned, the savings from the availability of competition to products like insulin glargine "hinge[s] on the level of competition." With one competitor on the market, prices fall slightly. According to the FDA and FTC, the point of greatest price reduction for pharmaceutical products is when the number of competitors goes from one to two.

~~68~~139. *Competition from ANDA-approved generics.* The introduction into the market of generics approved under § 505(j) as AB-rated generics to the reference branded product works dramatic, well-documented impacts on the sales and price of the product – generic penetration is rapid and thorough, price drops dramatically, and overall brand sales nearly vanish.

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[73] 37 C.F.R. § 42.108.

[74] 37 C.F.R. § 42.224

[75] 37 C.F.R. § 42.71.

[76] U.S. Patent & Trademark Office, "Trial Statistics IPR, PGR, CBM: Patent Trial and Appeal Board October 2017," *available at* https://www.uspto.gov/sites/default/files/documents/trial_statistics_october_2017.pdf.

~~69~~140. Due to the price differences between brand and generic drugs, and other institutional features of the pharmaceutical industry, the launch of a generic product results in the rapid shift of purchasers from brand to generic. Pharmacists ~~liberally and~~ substantially ~~substitutes~~substitute the generic drug when presented with a prescription for the brand drug. Since the passage of the Hatch-Waxman ~~Act~~Amendments, every state has adopted substitution laws requiring or permitting pharmacies to substitute generic drug equivalents for brand drug prescriptions (unless the prescribing physician specifically orders otherwise by writing "dispense as written" or similar language on the prescription).

~~70~~141. Thus, once a generic hits the market, it quickly erodes the sales of the corresponding brand drug, often capturing 80% or more of the market within the first six months after launch and 90% of the brand's unit drug sales after a year. This results in dramatic savings for drug purchasers. According to the Congressional Budget Office, generic drugs save consumers an estimated $8 to $10 billion a year at retail pharmacies. Even more billions are saved when hospitals use generics.

~~71~~142. *Competition from § 505(b)(2)-approved biologics or biosimilar products.* Follow-on biologics and biosimilar drugs are newer to the U.S. marketplace: the first one entered the market in 2015. The impact on sales, price, and penetration are therefore less understood than the nearly ubiquitous information about ANDA-approved generics. And there are differences in distribution, substitution laws, and prescription writing that make a direct analogy to ANDA-approved generics incomplete.

~~72~~143. However, numerous studies have been issued estimating the cost savings (determined by estimated price reductions, penetration, and the like) on the introduction of follow-on biologics and biosimilar drugs.

~~73~~144. A 2014 study by the Rand Corporation canvassed existing studies estimating the impact of the introduction of biosimilar products in the U.S. on price, absorption, and overall savings from the introduction of biosimilars.[77] Combining the results of these studies, Rand estimated overall ~~biosimilar~~ market penetration of 60 percent, and a biosimilar price discount due to competition of 35 percent. For the insulin market itself, Rand assumed 100 percent of the established insulin and growth hormone markets would be exposed to biosimilar competition in the next year (i.e., 2015, but that would turn out not to be, due to Sanofi's unlawful conduct to stall Lilly's entry), but with half the ~~biosimilar~~ penetration and price discounts of other markets. It observed that while the 35 percent price reduction estimate was on the high end of those included in the models it had analyzed, it acknowledged that the Congressional Budget Office had anticipated an even larger 40 percent reduction in the long term. All studies reviewed by Rand anticipated some amount of substantial price decreases ~~from biosimilar entry~~.

145. In 2017, Rand Corporation updated its earlier article based on empirical evidence from the emerging biosimilar market. It predicted that, in the insulin market alone, competition from biosimilar insulin products would save consumers between $2.4 and $6 billion in the coming years.[78] This, even though the authors of the study acknowledged that the market penetration and price discounts in the insulin market may be smaller than in other markets.

[77] Andrew W. Mulcahy, Zachary Predmore & Soeren Mattke, *The Cost Savings Potential of Biosimilar Drugs in the United States*, Rand Corporation (2014).

[78] Andrew Mulcahy, Jakub P. Hlavka & Spencer R. Case, *Biosimilar Cost Savings in the United States*, Rand Corporation (2017). Technically, insulins aren't biologics, since they were first approved under the FDCA and not the PHS. But the Rand study appears to be referring to insulin follow-on products when it makes these predictions.

C. Brand manufacturers ~~can~~ employ multiple tactics to block follow-on competition.

~~74~~146. Competition from lower-priced follow-on competitor drugs saves drug purchasers billions of dollars a year. These savings, however, mean lower profits for brand drug companies. Brand manufacturers thus seek to extend their monopolies for as long as possible, sometimes resorting to any means possible – including illegal means.

1. Brand companies can list an ineligible patent in the Orange Book.

147. ~~75.~~ First, brand manufacturers can game the system by listing in the Orange Book patents that do not in fact claim the drug product. Because the FDA performs merely a ministerial task in listing a patent in the Orange Book, the patent-listing system is easily manipulated by brand companies. As originally written, the Hatch-Waxman Amendments provided no mechanism by which a generic company could challenge patents that never should have been listed in the first place.

~~76~~148. In July 2002, the Federal Trade Commission ("FTC") published a study that reported on the growing industry trend for brand manufacturers to prevent or delay the marketing of generic drugs by submitting inaccurate or improper patent information to the FDA for listing in the Orange Book.[~~28~~79]

~~77~~149. The FTC report cited one case wherein a brand company facing patent expiration listed a new patent with the FDA in order to extend its right over the drug. Relying on the brand company's representation and unaware that the new patent listing, in fact, covered neither the drug's compound nor any method of using it, the FDA declined to approve the generic drug. In response, the generic ANDA applicant sued to remove the improper Orange Book patent listing, but the Federal Circuit found that it had no such right of action under the

[~~28~~79] *See* FTC, Generic Drug Entry Prior to Patent Expiration: An FTC Study, pp. iii-vi (July 2002).

Hatch-Waxman Amendments. Thus, the generic manufacturer's only option was to file a paragraph IV certification that immediately triggered the infringement suit and forced the generic to wait out the statutorily prescribed 30-month stay of ANDA approval by the FDA.[29][80] Put differently, an incorrect patent listing in the Orange Book could easily secure a brand company an additional two and a half years of monopoly profits.

150. In response to the high-profile case cited by the FTC study, Congress closed this "loophole." Congress recognized that brand companies were abusing the patent-listing process to delay competitors' market entry: "instead of spending all [of their] time developing new drugs," Senator Charles Schumer observed, brand companies were just "developing new patents."[81] Brand companies were "pull[ing] out all the stops to extend their monopolies," including "wild and crazy schemes."[82] So Congress added provisions to "end the abusive practices in the pharmaceutical industry which have kept lower-priced [follow-on drugs] off the market and cost consumers billions of dollars" by "end[ing] the practice of brand companies listing frivolous patents for the sole purpose of automatically delaying [competitors'] approval."[83]

[78]151. [To address these anticompetitive abuses,] Congress authorized generic manufacturers in patent infringement suits to assert a legal counterclaim challenging the brand manufacturer's submission of patent information to the FDA.[30][84] The applicable provision states that an applicant sued for patent infringement "may assert a counterclaim seeking an order requiring the [brand company] to correct or delete the patent information submitted" by the

[29][80] *Mylan Pharmaceuticals, Inc. v. Thompson*, 268 F.3d 1323 (Fed. Cir. 2001).

[81] 149 Cong. Rec. S8191 (daily ed. June 19, 2003).

[82] *Id.*

[83] 149 Cong. Rec. S15745-46 (daily ed. Nov. 24, 2003) (statement of Sen. Charles Schumer).

[30][84] *See* Medicare Prescription Drug, Improvement, and Modernization Act of 2003, 117 Stat. 2452.

brand company "on the ground that the patent does not claim either (aa) the drug for which the [brand company's NDA] was approved; or (bb) an approved method of using the drug."[31][85]

79152. Congress explained that this provision would "enforce the patent listing requirements at the FDA by allowing a [follow-on] applicant, when it has been sued for patent infringement, to file a counterclaim to have the brand drug company delist the patent or correct the patent information in FDA's Orange Book."[86] This statutory amendment provides recourse to a would-be competitor for improper patent information that is blocking FDA approval of its application. But it does not avoid delays in approval.

80. 153. Absent from this counterclaim provision was a qualifier that appeared in the second half of the FDA's listing test: the reasonableness of a brand company's belief that a patent might be listable. In other words, once a would-be competitor challenged the propriety of a listing on the ground that it did not claim a drug or method using that drug, the brand company could not keep listing the patent unless it prevailed in showing that the patent *actually* claimed either "the drug" or "an approved method of using the drug."

154. Courts evaluating claims that a patent was improperly listed in the Orange Book have dutifully applied this test. In a case involving a high-grade acetaminophen product, for example, a district court considering whether a patent listed in the Orange Book actually covered a novel "drug product" rather than just a process for making an old drug denied a motion to dismiss because it found that a would-be competitor had sufficiently alleged that the challenged patent was *actually* "outside the regulatory definition of a 'patent which claims the

[31][85] 21 U.S.C. § 355(j)(5)(c)(ii)(1).

[86] 149 Cong. Rec. S15745-46 (daily ed. Nov. 24, 2003) (statement of Sen. Charles Schumer); *see also* 149 Cong. Rec. S8195 (daily ed. June 19, 2003) (statement of Sen. Herb Kohl) (stating that the delisting counterclaim provision "will prevent brand name drugs [sic] companies from listing frivolous patents with the FDA in order to keep generics from being able to enter the market, and if they do, it will give generic companies recourse options.").

drug for which the applicant submitted the application or which claims a method of using such a drug"[87] – and later denied summary judgment because this question presented factual issues for the jury.[88] In another case, a district court considering an Orange-Book listed patent evaluated whether the patent *actually* claimed a method of using the relevant drug.[89] And in yet another case, *Buspirone*, a court *rejected* the notion that a challenge to the listing of a patent in the Orange Book can succeed only if the listing was "objectively baseless."[90]

2. Brand companies can assert improperly listed patents against would-be competitors to forestall competition.

155. Second, branded drug manufacturers can game the system by describing patents as containing drug product claims (even if the patents, in fact, do not do so), and then suing a would-be competitor that files a paragraph IV certification, even though that lawsuit lacks all merit (i.e., even if the competitor's product does not actually infringe any ~~properly-listed~~properly listed patent). Regardless of merit, filing of the suit delays final FDA approval of a § 505(b)(2) application for up to 30 months.

~~81~~156. Simply by suing on an Orange-Book-listed patent within 45 days (even if the patent should not have been listed, or was misidentified, and even if the suit would fail if ever permitted to go to an ultimate conclusion), the brand manufacturer automatically prevents the FDA from granting final approval to the would-be competitor's application until the earlier of

[87] *Cadence Pharms., Inc. v. Fresenius Kabi USA, LLC*, No. 13-cv-139, 2013 WL 12075975 (S.D. Cal. June 26, 2013).

[88] *Cadence Pharms., Inc. v. Fresenius Kabi USA, LLC*, No. 13-cv-139, 2014 WL 12139078 (S.D. Cal. June 5, 2014).

[89] *Mylan Pharms. Inc. v. Thompson*, 139 F. Supp. 2d 1 (D.D.C. 2001) (deciding a pre-MMA improper Orange Book listing claim by examining whether the patent *actually* claimed "the drug" or "an approved method of using the drug"), *reversed on other grounds*, 268 F.3d 1323 (Fed. Cir. 2001) (reversing because the statutory framework did not, at that time, provide a counterclaim), *abrogation of appellate decision by statute recognized by Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 339 (2012).

[90] *In re Buspirone Patent Litig.*, 185 F. Supp. 2d 363 (S.D.N.Y. 2002) (rejecting a reasonableness test for ministerial filings with the FDA).

(a) the passage of 30 months, or (b) the issuance of a decision by a court that the patent is invalid or not infringed by the competitor's application.

~~82~~157. That branded drug manufacturers often sue generic drug manufacturers under the Hatch-Waxman Amendments simply to delay drug competition – as opposed to enforcing a valid patent that is actually infringed by the competitor's drug – is demonstrated by the fact that, in 73% of the paragraph IV litigation cases ~~studied~~decided on the merits, the brand company lost ~~on the merits~~, or was forced to dismiss the suit.

158. Third, filing a sham lawsuit asserting a patent on which a reasonable pharmaceutical company would have no objectively reasonable expectation of success in proving a patent valid, enforceable, and infringed creates a pretextual need to settle that litigation to avoid certain loss, and enables a brand company to leverage meritless patent allegations into settlements that further delay competition.

V. FACTS

A. Diabetes: a deadly but treatable disease.

~~83~~159. The number of Americans who live with diabetes has exploded in the last half century. In 1958, only 1.6 million people in the United States had diabetes. By the turn of the century, that number had grown to over 10 million. Just 14 years later, the headcount tripled again. Now over 29 million people – 9.3 percent of the country – live with the disease. And this trend does not appear to be slowing: 86 million Americans have prediabetes, a health condition that significantly increases a person's risk of type 2 diabetes.

~~84~~160. Diabetes occurs when a person has too much glucose – sugar – in her blood stream. A lack of insulin or diminished responsiveness to insulin causes the process to break down, leading to high blood sugar levels. If left unchecked, high blood sugar levels lead to diabetes.

~~85~~161. There are two basic types of diabetes. Ninety to ninety-five percent of Americans living with diabetes developed the disease because they do not produce enough insulin or have become resistant to the insulin their bodies do produce. Known as type 2, this more common form of diabetes is typically associated with increased body weight and is often developed later in life. In contrast, type 1 diabetes occurs when a patient completely ceases insulin production. This form of diabetes is usually diagnosed in children and young adults, but can occur at any age.

~~86~~162. If left untreated or under-treated, diabetes is debilitating, and potentially deadly: it remains the seventh leading cause of death in the United States, despite the availability of effective treatments. But despite its potential lethality, diabetes is very treatable.

B. Insulin: a century of patent protection.

~~87~~163. An effective treatment for diabetes, insulin, has been available for almost a century.

1. Insulin's unselfish beginnings.

~~88~~164. In 1922, two men – orthopedic surgeon Frederick Banting and medical student Charles Best – pioneered a technique for removing active insulin from an animal pancreas, for injection into humans with diabetes.

~~89~~165. ~~Banting and Best's discovery was striking, and not only because it represented a medical breakthrough.~~ At first, neither Banting nor Best applied for a patent on their game-changing innovation because they wanted their discovery to be open to the public, available to all for use. When the two eventually did patent the drug, it was only to protect its availability to the public: Banting and Best realized that if they did not patent their drug, someone else would. They sold their insulin patent to the University of Toronto for $1 each, hoping to

ensure that, "[w]hen the details of the method of preparation are published anyone would be free to prepare the extract, but no one could secure a profitable monopoly."~~92~~91

~~90~~166. University of Toronto researchers teamed up with Eli Lilly, and agreed that Lilly could apply for U.S. patents on any manufacturing process improvements. They reached similar agreements with a few other companies, including Denmark's Nordisk Insulinlaboratorium and Novo Terapeutisk Laboratorium, two companies that later merged to form Novo Nordisk.

~~91~~167. Flouting Banting and Best's intentions, those companies quickly set to work shielding insulin behind a wall of patents. Over the next 90-plus years, pharmaceutical researchers sought to secure and extend a monopoly in the insulin market. Research spawned multiple types of insulin – animal insulin, long-acting animal insulin, human insulin, analogue insulins, rapid-acting analogue insulins, and long-acting insulins – each shielded by layers of patents licensed to pharmaceutical companies that had forgotten the generosity of Banting and Best.

2. Animal insulin: the insulin patent parade begins.

~~92~~168. The original animal insulin was short acting – it only had an effect on patient blood sugar levels for three to six hours. In the early 1930s, however, scientists at Nordisk created long-acting animal insulin. In 1946, researchers added zinc to form the crystalline protamine-isophane insulin, now known as neutral protamine Hagedorn (NPH), making it possible to combine long-acting and short-acting insulin into one product and allowing many diabetes patients to take a single daily injection. Soon afterward, a method for prolonging the action of insulin without adding protamine was discovered. These innovations offered

~~92~~91 M. Bliss, *The Discovery of Insulin* (2013).

important new options for the dosing of insulin. But they also extended the reach of insulin patents into the 1970s.

3. Human insulin.

~~93~~169. In the late 1970's, just as these animal-based insulin patents were expiring, researchers began to produce human insulin through recombinant technology. By 1982, Eli Lilly brought the first recombinant human insulins to the U.S. market.

~~94~~170. Around the same time, Novo and Nordisk developed methods for chemically converting bovine insulin into human insulin. The advent of these new human insulins also enabled Lilly and Novo Nordisk to spin a fresh web of insulin patents, which stretched into the 21st century.

4. Rapid-acting insulin analogues.

~~95~~171. In the mid-1980s, scientists learned to modify the molecular structure of insulin and improve its physiological effects. By 1996, Eli Lilly had obtained approval for the first rapid-acting, man-made insulin. This new type of insulin – known as an analogue – allowed for substantially faster absorption. Never far behind Lilly, Novo Nordisk released its own analogue in 2000.

~~96~~172. Four years later, Sanofi entered the insulin-patent game, releasing another rapid-acting analogue. Another round of patents over these new products further extended these three company's monopoly over insulin markets.

5. Long-acting insulin analogues.

~~97~~173. In 2000, Sanofi released the first long-acting analog. This drug was branded as Lantus (insulin glargine). Five years later, Novo Nordisk gained approval for its own long-acting analog, Levemir (insulin detemir). The main patents on these long-acting products expired in June 2014, nearly a century after Banting and Best's first patent application in 1923.

~~98~~174. Insulin glargine and insulin detemir are not the same product. While both are basal insulin formulas (i.e., they last for a long time in the body and act as background insulin, with a slow feed that mimics the constant low output of insulin produced by a healthy pancreas) they are also differentiated.

~~99~~175. Insulin glargine (marketed until mid-December of 2016 as only Lantus and Lantus SoloSTAR) is a clear formula made with glargine, a genetically modified form of human insulin, dissolved in a special solution. Human insulin is made of two amino acid chains, called A and B, that have two disulfide bonds between them. In glargine, one amino acid has been switched out, and two extra amino acids have been added to one end of the B chain. The modifications make glargine soluble at an acidic pH, but much less soluble at the neutral pH that is found in the body.

~~100~~176. Before it is injected into the body, insulin glargine is maintained completely dissolved in an acidic solution: it is produced by a vat of E. coli bacteria; then purified and added to a solution containing zinc and glycerol; and hydrochloric acid is added, resulting in the solution having a pH of about 4. When injected into subcutaneous tissue, the acidic insulin glargine solution meets an environment with a neutral pH. Because glargine is not soluble at a neutral pH, it precipitates, for falls out of its watery solution, and becomes relatively insoluble. Small amounts slowly move back into solution over time and then to the bloodstream, making the product long-acting.

~~101~~177. Insulin detemir works differently. Like insulin glargine, it is formed through recombinant DNA technology, but is produced by baker's yeast instead of E. coli. Like insulin glargine, some amino acids in the molecule have been replaced. But instead of being replaced with different amino acids, detemir's amino acid is substituted with a fatty acid.

Manitol is used instead of glycerol. And detemir may be made acidic using sodium hydroxide instead of hydrochloric acid. Unlike insulin glargine, insulin detemir does not form a precipitate upon injection. Instead, detemir's molecules stick to one another when injected into a neutral-pH environment, so it is slowly absorbed. Once the detemir molecules dissociate from each other, they readily enter the blood stream, where the added fatty acid binds to albumin. More than 98 percent of detemir in the bloodstream is bound to albumin. With the albumin stuck to it, the insulin cannot function. Because it slowly dissociates from the albumin, it is available to the body over an extended period.

~~102~~178. Insulin glargine and insulin detemir are different molecules, and are not reasonably interchangeable. Because insulin glargine achieves its long-acting effect through insolubility in the human body, while insulin detemir achieves a similar effect through its binding properties (first to itself, then to albumin), they drugs have different mechanisms of action. And insulin glargine is, obviously, not equivalent to animal insulin, human insulin, or the rapid-acting human insulin analogues.

C. The compound patent for insulin glargine.

~~103~~97. In August of 1997, the Patent and Trademark Office ("PTO") issued U.S. Patent No. 5,656,722 ("the '722 patent") for insulin glargine to a German inventor. Exhibit A to this complaint is a copy of the '722 patent. The patent was assigned to Hoechst AG,~~a~~

179. A German chemicals life-sciences company that became Aventis Deutschland after a merger with France's Rhône-Poulenc S.A. in 1999. With the new company's 2004 merger with Sanofi- Synthélabo, it became a subsidiary of the resulting Sanofi-Aventis pharmaceuticals group.

~~104~~180. The '722 patent claimed insulin glargine, and also disclosed the addition of zinc, m-cresol, glycerol, water, and pH adjusted by solutions of hydrochloric acid (HCl) and sodium hydroxide (NaOH), as used in the Lantus formulations approved by the FDA in April 2000. Ex. A, col. 5, lines 32-40, 47, 52-57.

~~105~~181. The '722 patent expired on August 12, 2014. Pursuant to FDA regulation, Sanofi earned an additional period of pediatric exclusivity extending to February 12, 2015.

D. The approval of Lantus, the first insulin glargine injection.

~~106~~182. On or about April 20, 2000, the FDA approved NDA No. 21-081 for Lantus (insulin glargine [rDNA origin] injection).

~~107~~183. Sanofi listed the '722 patent in the Orange Book.

~~108~~184. Lantus is a sterile solution of insulin glargine for use as an injection.

~~109~~185. As first approved, Lantus was indicated for once-daily subcutaneous administration at bedtime in the treatment of adult and pediatric patients with type 1 diabetes mellitus or adult patients with type 2 diabetes mellitus who require basal (long-acting) insulin for the control of hyperglycemia. Its potency is approximately the same as human insulin, and it exhibits a relatively constant glucose-lowering profile over 24 hours that permits once-daily dosing.

~~110~~186. When Lantus was originally approved by the FDA, it had two package forms:

(1) vials (5 and 10 mL) for use with single-dose syringes, and (2) cartridges (3 mL) for use in an injector pen Sanofi called "OptiPen™ One." Different pens are marketed for use by diabetic patients to inject their insulins.

~~111~~187. Sanofi is the holder of NDA No. 21-081.

~~112~~188. Sanofi possesses a copy of NDA 21-081 and any supplements and amendments thereto, and it possesses a copy of the communications with the FDA regarding approval by the FDA of NDA No. 21-081 and any supplements and amendments thereto.

~~113~~189. Sanofi possesses documents evidencing the identity of the active and inactive ingredients of the insulin glargine [rDNA origin] injection products that have been prescribed and sold in the United States under NDA No. 21-081.

~~114~~190. The FDA's letter approving NDA No. 21-081 included the following statement: "The final printed labeling (FPL) must be identical to the submitted draft labeling ((1) package insert submitted April 20, 2000, (2) patient package inserts [for vials and cartridges] submitted April 20, 2000, (3) OptiPen™ One User Manual dated April 18, 2000, and (4) immediate container and carton labels [for 5 mL and 10 mL vials and 3 mL cartridges] submitted April 18, 2000)." In other words, the FDA considered the pre-filled cartridges to be "containers."

~~115~~191. The draft package insert for NDA No. 21-081 having a date of submission of April 20, 2000, included the following statement: "Each milliliter of LANTUS (insulin glargine injection) contains 100 IU (3.6378 mg) insulin glargine, 30 mcg zinc, 2.7 mg ~~m-cresol~~m- cresol, 20 mg glycerol 85%, and water for injection. The pH is adjusted by addition of aqueous solutions of hydrochloric acid and sodium hydroxide."

~~116~~192. Exhibit B to this complaint is a copy of the draft package insert for NDA 21- 081 bearing a date of submission of April 20, 2000.

~~117~~193. At some point on or about the time of approval of Lantus, Sanofi caused the '722 patent to be listed in the Orange Book. Over the years, the Orange Book identified Lantus as a single product made in two formulations~~, "injectable" (i.e.,~~ the "vial formulation~~,~~"

which was initially sold in 5 mL and 10 mL amounts~~)~~, and the "~~injection~~"cartridge formulation," used with an OptiClick injector pen ~~(i.e., the "cartridge formulation")~~. The listing of the '722 patent did not distinguish between the two formulations (as the '722 patent claimed the drug substance and drug product contained in both).

E. The launch and sale of Lantus.

~~118~~194. After approval by the FDA of NDA No. 21-081, in May 2001 Lantus was launched for sale in the United States. Lantus was prescribed and sold in the United States from May 2001 through the present.

~~119~~195. Each milliliter of Lantus prescribed and sold in the United States at times after approval by the FDA of NDA No. 21-081 (including the period before September 9, 2001) contained 100 IU (3.6378 mg) insulin glargine, 30 mcg zinc, 2.7 mg m-cresol, 20 mg glycerol 85%, and water for injection, and the pH was adjusted by addition of aqueous solutions of hydrochloric acid and sodium hydroxide.

~~120~~196. From the launch of Lantus in May 2001 through to February 2015, sales of the product were protected by the '722 patent and its listing in the Orange Book. As a result, the sales of Lantus were protected for almost 15 years – from launch until February 2015 – from competition from generic or follow-on insulin glargine products.

~~121~~197. This lawsuit does not challenge Sanofi's rights to charge supra-competitive prices for Lantus products up until February of 2015. But it does challenge Sanofi's unlawful conduct in prolonging its exclusive position beyond February of 2015, i.e., beyond the expiration of the '722 patent.

~~122~~198. During Sanofi's period of lawful exclusivity, it realized staggering profits. In 2014 alone, U.S. gross sales for Lantus products were $7.87 billion.

F. The 2005 vial supplement.

~~123~~199. In 2005, five years after Lantus was approved, Sanofi received FDA approval to add an ingredient, polysorbate 20, to the 10 ml Lantus vial formulation.

~~124~~200. On March 15, 2005, the FDA approved Supplemental NDA No. 21-081/S-017 (the "2005 vial supplement"). Exhibit C to this complaint is a copy of the March 2005 supplement approval. The FDA characterized this supplement as a change to "Manufacturing (CMC)-Formulation" – indicating that it was approving a new formulation of Lantus.[92]

~~125~~201. The 2005 vial supplement provided for the addition of 20 ppm of polysorbate 20 to each 10 mL vial of Lantus (by this time, Sanofi had pulled the 5 mL option off the market).

~~126~~202. The supplemental new drug application did *not* provide for the addition of polysorbate 20 to the 3 mL *cartridge* formulation of Lantus; the Lantus cartridge formulation for use in the OptiPen One injector pen remained unchanged.

G. The 2007 approval and launch of Lantus in SoloSTAR packaging.

~~127. In 2007, Sanofi received an approval from the FDA for a "package change" – allowing Sanofi to sell Lantus in another, disposable, injector pen called SoloStar. Exhibit D to this complaint is a copy of the package change approval.~~

203. On April 24, 2006, Sanofi sent the FDA a supplemental new drug application (SNDA) that proposed adding a new disposable insulin pen device, Lantus SoloSTAR.[93] This supplement proposed no changes to Lantus vials, Lantus cartridges, or the OptiClick injector.

[92] *See* Approval Date(s) and History, Letters, Labels, Reviews for NDA 021081, Drugs@FDA, *available at* https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=021081 (listing 3/15/2005 Suppl-17 as a formulation change).

[93] The FDA's website refers to this as "SUPPL-24."

The FDA described the new supplement as "provid[ing] for a new disposable insulin delivery device (SoloStar) for use with Lantus."

204. SoloSTAR was not approved as a drug delivery system. Although the FDA's approval letter called SoloSTAR a "disposable insulin injection device," its treatment of the SNDA reveals it considered the pen to be packaging. Throughout the FDA's review of the Lantus SoloStar SNDA, the FDA referred to the SoloSTAR pen as a container and as packaging. Sanofi itself also referred to SoloSTAR pen as a container and as packaging. The FDA's regulatory review package covering this proposed amendment is attached as Exhibit N.

205. Sanofi provided, as required, proposed labeling for both the carton (meaning language appearing on the cardboard box that SoloStar pens come in) and for the SoloStar pen itself (meaning language appearing on the sticker affixed to the pen). In connection with reviewing Sanofi's proposed labeling for the pen, the FDA repeatedly referred to the pen as a container:

- The FDA "review[ed] ... the March 14, 2007, carton label and March 14, 2007 *container* (SoloStar pen) label for Lantus SoloStar";
- In listing the labeling materials Sanofi had submitted, the FDA included the "SoloStar pen – *container*" and, separately, the "SoloStar pen – carton";
- In a memo describing the FDA's Division of Medical Errors and Technical Support's review of the label and packaging of Lantus SoloSTAR, the division reported that it reviewed both the "*container* and carton labeling," and then listed issues with the "pen label" and the "carton label."
- In a memo written by the FDA, under the heading "Space on the pen label to record the date of initial use," the FDA states "the ideal placement [for the date of initial use] would be on the *container* label of in-use pens."

206. The FDA's treatment of the SoloSTAR pen as a container is consistent with its broader policies. In a 2015 draft FDA guidance titled "Selection of the Appropriate Package Type Terms and Recommendation for Labeling Injectable Medical Products Packaged in

Multiple-Dose, Single-Dose, and Single-Patient-Use containers for Human Use," the FDA refers to "an insulin pen that contains multiple doses of insulin for individual patient use" as a "'single-patient use' *container*."

207. The FDA also repeatedly referred to the SoloSTAR pen as packaging:

- In an FDA memo, FDA states "the SoloStar cartridge holder into which the 3ml cartridge is irreversibly attached, is considered *secondary packaging*. No part of the SoloStar has contact with the drug product."

- In a March 21, 2007 request for consultation, FDA refers to Sanofi's SNDA for Lantus SoloSTAR as "this new *packaging* supplement. The supplement provides for a new pen injector for the insulin analog Lantus."

208. The FDA regulatory files for its review of the SoloSTAR SNDA includes an email between Sanofi officials and the FDA, discussing proposed changes to the label affixed to the SoloSTAR pen. The email recounts the FDA's suggestion that Sanofi leave a space on the pen itself for users to write the date on which the pen was first used. Michael Lutz, of Sanofi's Regulatory Development department and the FDA's primary point of contact on the Lantus SoloSTAR supplement, responded, referring to the pen as a container:

> There is no room for the patient initial use date because label wraps around to the lot number, expiration date and manufacturer's mark. We have placed it in the white oval below the concentration. *See Container Label (pen label).*[94]

209. On April 25, 2007, the FDA approved Sanofi's Lantus SoloSTAR SNDA, characterizing it in the Approval History as a "package change." This entitled Sanofi to sell Lantus in a disposable injector pen called SoloStar. Exhibit D to this complaint is a copy of the package change approval. The approval letter confirms that the FDA did not view this as a formulation change, as it had when Sanofi added polysorbate 20 to the vials of Lantus. Instead,

[94] In the response email, the FDA again explained the "ideal placement" for the initial use date was on the "container label of in-use pens." But it ultimately agreed that the initial-use date could instead be placed on the "carton."

the FDA characterized this supplement as a change to "Labeling-Container/Carton Labels, Labeling-Package Insert" – i.e., a change to the way Lantus was packaged.[95]

210. In Sanofi's label for Lantus SoloSTAR, approved by the FDA along with the addition of the SoloSTAR packaging, Sanofi itself described Lantus as being available in three different "package size[s]," then lists "The SoloSTAR pen" as one of the three.

211. Given the FDA's statements – and Sanofi's too – it was unreasonable for Sanofi to believe that its SNDA approval was for anything other than a package change.

~~128~~212. Each milliliter of Lantus included in the SoloSTAR pen contains 100 Units (3.6378 mg) insulin glargine, 30 mcg zinc, 2.7 mg m-cresol, 20 mg glycerol 85%, and water for injection, and the pH is adjusted by addition of aqueous solutions of hydrochloric acid and sodium hydroxide. It does *not* contain polysorbate 20.

~~129. With the addition of Lantus SoloSTAR, Lantus products were approved in three product formulations, the original 10 mL vials (NDC 0088-2220-33), the original 3 mL cartridge system using the OptiClik injector pen, package of 5 (NDC 0088-2220-52), and the new 3 mL SoloSTAR disposable insulin device, package of 5 (NDC 0088-2220-60). Only the vial formulation provided for the addition of 20 ppm of polysorbate 20; the other two did not.~~

213. Only the vial formulation provided for the addition of 20 ppm of polysorbate 20; the other two did not.

214. At the time, Sanofi had not yet acquired patents covering the SoloSTAR pen. And so, from 2007 through 2011, Sanofi did not own any patents covering the SoloSTAR pen; nor did it list any in the Orange Book.

[95] *See* Approval Date(s) & History, Letters, Labels, Reviews for NDA 021081, Drugs@FDA, available at https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=021081 (Suppl. 24).

H. The Lantus polysorbate vial formulation patents.

~~130.~~ ~~Back on~~215. On September 9, 2002, two Sanofi scientists had filed a provisional application with the PTO seeking patent protection for a pharmaceutical formulation.

~~131~~216. On January 13, 2009, the PTO issued U.S. Patent No. 7,476,652 ("the '652 patent"), entitled "Acidic Insulin Preparations Having Improved Stability." The '652 patent expires July 23, 2023, with a six-month period of pediatric exclusivity extending until January 23, 2024. A true and correct copy of the '652 patent is attached as Exhibit E to this complaint.

~~132~~217. On May 11, 2010, the PTO issued U.S. Patent No. 7,713,930 ("the '930 patent"), entitled "Acidic Insulin Preparations Having Improved Stability." The '930 patent expires June 13, 2023, with a period of pediatric exclusivity extending to December 13, 2023. A true and correct copy of the '930 Patent is attached as Exhibit F to this complaint.

~~133~~218. By assignment, Sanofi Aventis Deutschland GmbH ("Sanofi GmbH") – an affiliate of Sanofi U.S. – owns all right, title, and interest in and to the '652 and '930 patents. It licenses exclusively to Sanofi U.S. all rights under the '652 and '930 patents, including the rights to sell and offer to sell in the United States the technologies, products, or services claimed by them. But neither Sanofi GmbH nor Sanofi U.S. has the right to assert rights in those patents beyond the scope of the claims contained in them.

~~134~~219. The '652 and '930 patents set forth examples of an insulin glargine formulation in which polysorbate 20 or 80 was added. Ex. E, cols. 5-10; Ex. F, cols. 6-11. The patents claim a formulation requiring use of "polysorbate 20," "polysorbate 80," "polysorbate[s]" or "poloxamers."

~~135~~220. The '652 and '930 patents are herein referred to as the "polysorbate vial patents."

~~136~~221. Sanofi tried during prosecution of the '652 patent to obtain broader claims, but the patent office examiner repeatedly rejected them over prior art. In the '930 patent, which has the same examples as the '652 patent, a different patent examiner allowed patent claims requiring use of "esters [or] ethers of polyhydric alcohols." The '652 patent examiner had specifically rejected this language as unpatentable.

~~137~~222. Because the Lantus polysorbate vial formulation patents are based on applications filed in the U.S. on September 9, 2002, they are governed by the "pre-AIA" version of patent law. The "critical date" for prior art to these patents under 35 U.S.C. § 102(b) is therefore September 9, 2001. Section 102(b) prior art includes subject matter on sale or in public use in the U.S. before the critical date.

I. The polysorbate vial formulation patents do not cover the formulations for the Lantus cartridge or Lantus SoloSTAR.

~~138~~223. Insulin glargine, zinc, m-cresol, glycerol, water, hydrochloric acid, and sodium hydroxide are not polysorbate.

~~139~~224. Insulin glargine, zinc, m-cresol, glycerol, water, hydrochloric acid, and sodium hydroxide are not poloxamers.

~~140~~225. Insulin glargine, zinc, m-cresol, glycerol, water, hydrochloric acid, and sodium hydroxide are not esters of a polyhydric alcohol.

~~141~~226. Insulin glargine, zinc, m-cresol, glycerol, water, hydrochloric acid, and sodium hydroxide are not ethers of a polyhydric alcohol.

~~142~~227. The cartridge formulation of Lantus does not contain a polysorbate.

~~143~~228. The cartridge formulation of Lantus does not contain a poloxamer.

~~144~~229. The cartridge formulation of Lantus does not contain an ester of a polyhydric alcohol.

~~145~~230. The cartridge formulation of Lantus does not contain an ether of a polyhydric alcohol.

~~146~~231. The cartridge formulation of Lantus is not within the scope of any independent claim of the '652 patent.

~~147~~232. The 3 mL cartridge presentation of Lantus is not within the scope of any independent claim of the '930 patent.

~~148~~233. Lantus in the SoloSTAR packaging does not contain a polysorbate.

~~149~~234. Lantus in the SoloSTAR packaging does not contain a poloxamer.

~~150~~235. Lantus in the SoloSTAR packaging does not contain an ester of a polyhydric alcohol.

~~151~~236. Lantus in the SoloSTAR packaging does not contain an ether of a polyhydric alcohol.

~~152~~237. Lantus in the SoloSTAR packaging is not within the scope of any independent claim of the '652 patent.

~~153~~238. ~~The~~ Lantus in the SoloSTAR ~~product~~packaging is not within the scope of any independent claim of the '930 patent.

J. Sanofi ~~wrongfully~~improperly listed the polysorbate vial formulation patents in the Orange Book.

~~154~~239. Following the issuance of each of the polysorbate vial formulation patents in 2009, Sanofi listed the '652 patent and the '930 patent to be identified in the Orange

Book as indiscriminately claiming "LANTUS" in all of its product formulations, both vial and cartridge.

~~155.~~ ~~Under~~240. Recall that, under the Hatch-Waxman Amendment and applicable regulations, the FDA requires that an NDA holder submit information identifying *only* a "patent which claims the drug for which the application was submitted or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C. § 355(b)(1)(G).

~~156~~241. The '652 patent and the '930 patent *arguably* claim the vial formulation of Lantus (as now modified to add the polysorbate). But they do *not* claim Lantus in ~~its~~ cartridge ~~formulations, i.e., the original Lantus OptiClik injector pen, and the Lantus~~or the SoloSTAR ~~disposable insulin device~~packaging. So they should not have been identified in the Orange Book as applicable to ~~the two cartridge formulations~~those packages of Lantus.

~~157~~242. However, when providing information to the FDA, Sanofi did not clearly delineate the scope of the '652 and '930 patents. It falsely and misleadingly indicated to the FDA that both patents covered ~~the two injector formulations.~~Lantus in the cartridges and SoloSTAR packaging. This required competitors who wished to make versions of insulin glargine in cartridges or a pen to certify under paragraph III (and wait until the patents expired) or paragraph IV (and challenge) to these inapplicable patents. It also meant that, if Sanofi asserted these patents with respect to cartridges or pens, it could trigger a 30-month stay.

~~158~~243. This ~~wrongful~~incorrect listing of the '652 patent and the '930 patent in the Orange Book as covering the Lantus cartridge formulations ~~persisted through the 33rd edition (2013) of the publication~~persists to date.

K. The rise of proprietary insulin pens.

244. Beginning in the mid-1980s, insulin makers began selling their analog insulin products in proprietary auto-injector pens. Novo Nordisk, for example, launched the first pen injector (NovoPen) and went on to develop the FlexPen, the Flextouch, and the FlexPro. Sanofi had the Optipen and, of course, SoloSTAR. And Lilly had the KwikPen. In all, there were more than a dozen pen devices available in the U.S.:

Byetta® exenatide injection
5 mcg

Byetta® exenatide injection
10 mcg

HumaPen® MEMOIR™

HumaPen® LUXURA™ HD

Humulin N® Pen
Humulin® 70/30 Pen

NovoPen® 3

Humalog® Pen
Humalog® 75/25™ Pen
Humalog® 50/50™ Pen

NovoPen® Junior

Forteo® Pen

Novolog® Mix 70/30 FlexPen®

Humalog® KwikPen™

Levemir® FlexPen®

OptiClik® Pen for
Lantus® and Apidra®

Lantus® SoloSTAR®

AutoPen®

Apidra® SoloSTAR®

Victoza® liraglutide injection

SymlinPen® 60
SymlinPen® 120

245. While, broadly speaking, each company's pen performed an apparently similar function (i.e., injecting a form of insulin), each pen had different features, benefits, and limitations. For example, Lilly claims that KwikPen depresses further to provide patients more certainty that its dose was actually dispensed. Sanofi differentiates its SoloSTAR pen from

other injection pens (including KwikPen) by touting its compatibility with smaller needles, its large-print dosing window, its push-button injection feature, and its ability to dispense larger doses. Sanofi also touts the fact that its SoloSTAR required at least 30% less force to dispense insulin than other leading disposable pens, including Lilly's KwikPen.

~~K~~L. Sanofi ~~collects~~and DCA obtain a series of injector pen patents.

~~159.~~ ~~In or around~~246. Between 2011 and 2013, ~~Sanofi —~~in an effort to build a portfolio to block competition to its Lantus franchise~~ — began to collect~~, Sanofi and its partner DCA Design International obtained a series of injector pen patents~~.~~ that allegedly covered the SoloStar pen, or features of the SoloStar pen. None of these patents claim insulin glargine.

247. In the early 2000's, Sanofi teamed up with DCA to develop the SoloSTAR pen. DCA has touted the work it has done for Sanofi as including "design planning, usability and HF, mechanical engineering, industrial design, color, material and finish, instructional design, graphic design, prototyping, testing and evaluation, and production support." DCA "partnered with Sanofi throughout the development of SoloStar."

~~160~~248. In March 2003, ~~a design company called DCA Design International, Ltd. from Warwick, England had~~DCA filed a British patent application directed to a particular approach to an injector pen. That application spawned numerous ~~different~~ continuing applications, resulting in various patents.

~~161~~249. On April 5, 2011, the PTO issued United States Patent No. 7,918,833 ("the '833 patent"), entitled "Pen-Type Injector." The '833 patent expires September 23, 2027, with a period of pediatric exclusivity extending to March 23, 2028. On September 28, 2011, the patent was assigned to Sanofi-Aventis Deutschland GmbH. A true and correct copy of the '833 patent is attached as Exhibit G to this complaint.

~~162~~250. On August 20, 2013, the PTO issued United States Patent No. 8,512,297 ("the '297 patent"), entitled "Pen-Type Injector." The '297 patent expires September 15, 2024. A true and correct copy of the '297 patent is attached as Exhibit H to this complaint.

~~163~~251. On October 15, 2013, the PTO issued United States Patent No. 8,556,864 ("the '864 patent"), entitled "Drive Mechanisms Suitable for Use in Drug Delivery Devices." The '864 patent expires March 3, 2024. A true and correct copy of the '864 patent is attached as Exhibit I to this complaint.

~~164~~252. On December 10, 2013, the PTO issued United States Patent No. 8,603,044 ("the '044 patent"), entitled "Pen-Type Injector." The '044 patent expires March 2, 2024. A true and correct copy of the '044 Patent is attached as Exhibit J to this complaint.

~~165~~253. The '833 patent, the '297 patent, the '864 patent and the '044 patent are herein called the "~~DCA~~initial injector pen patents~~.~~" ~~All of the DCA~~(since Sanofi would later go on to add more than a dozen more patents). All of the initial injector pen patents are based on ~~DCA Design's~~DCA's one British patent application filed in March 2003.

~~166~~254. In or before August of 2013 for the '833 patent, and shortly after PTO issuance for the '297, '864 and '044 patents, Sanofi GmbH acquired all right, title, and interest in and to those patents, and Sanofi U.S. became an exclusive licensee ~~of them~~.

~~L~~M. ~~Sanofi rearranges its~~The initial injector pen patents were not eligible for Orange Book ~~listings to create a patent roadblock to follow-on competition~~listing.

255. As described above, the FDCA sets forth a two-part test as to whether an NDA holder may/must submit patents ostensibly covering its approved product for listing in the Orange Book.

256. First, the patent must claim "the drug . . . or . . . a method of using such drug." A patent claims "the drug" if it claims the finished dosage form *that contains the drug substance* (that is, the active ingredient). The patent either does or does not claim "the drug."

257. If the patent does claim the finished dosage form that contains the drug substance, then one moves on to the second part of the test. But if the patent claims only a container or packaging and *not* the active ingredient, then the regulations prohibit the NDA holder from asking the FDA to list the patent. If the NDA holder fails the first part of the test, there is no "reasonableness" defense.

258. Second, if the first criterion is satisfied, the patent must be one that "could reasonably be asserted" against a proposed competitor product. The "reasonableness" standard only applies to this second prong.

259. An NDA holder may only submit information for a patent, and ask the FDA to list that patent in the Orange Book, if both criteria are met.

260. So when it comes to determining the propriety of asking the FDA to list a patent under the auspices that it claims the drug product, the relevant question is *not* whether the approved drug product includes both the container and the active ingredient. The correct question is whether the patent to be listed claims (1) the finished dosage form (2) with the drug substance as well as the container.

1. Sanofi's initial injector pen patents do not claim the finished dosage form of Lantus.

261. The Orange Book lists the dosage form and route of administration for each approved product. At the time Sanofi first submitted patent information asking the FDA to list the '833 pen patent, Sanofi identified the dosage form of Lantus as an "injectable" and the route of administration as "injection."[96]

262. Only the insulin glargine itself can be "injectable": a pen is not "injectable." A pen can be used to "inject" something that is "injectable," or to administer an "injection," but the pen

[96] Pursuant to regulation, it is up to the manufacturer to identify the relevant form of the drug when submitting information about a newly approved drug for listing in the Orange Book. 21 C.F.R. § 314.53(c)(2)(i)(F).

can be used to "inject" something that is "injectable," or to administer an "injection," but the pen itself is not injectable.

263. Although the FDA approved insulin glargine in the SoloSTAR injector pen, that is irrelevant to determining which patents should be listed in the Orange Book: "[t]he key factor is whether *the patent* being submitted claims the *finished dosage form* of the approved drug product." Patents that cover other aspects of the SoloSTAR packaging can be enforced through other means.

264. Sanofi's initial injector pen patents do not claim an "inject*able*." They claim either a type of inject*or* or elements of an inject*or*.

2. The initial injector pen patents do not claim insulin glargine (or insulin).

~~167. As explained above, § 505(b)(1) of the FDCA allows NDA holders to list *only* patents which "claim[] the drug" or "a method of using such drug," and only if "a claim of patent infringement could reasonably be asserted" against a would-be competitor.[33] FDA regulation 21 C.F.R. § 314.53(b) (1999) & (2002) provides that "[f]or patents that claim a drug substance or drug product, the [NDA] applicant shall submit information only on those patents that *claim a drug* product that is the subject of a pending or approved application, or that claim a *drug* substance that is a component of such a product."[34]~~

~~168. Patents claiming something *distinct* from the relevant drug product or drug substance (e.g., patents claiming only packaging or a container) "fall outside of the requirements of patent submission", and so must not be submitted.[35] "However," the Agency~~

~~[33] 21 U.S.C. § 355(b)(1).~~

~~[34] 21 C.F.R. § 314.53(b) (1999) & (2002). (emphasis added).~~

~~[35] *Applications for FDA Approval to Market a New Drug: Patent Submission and Listing Requirements and Application of 30-Month Stays on Approval of Abbreviated New Drug Applications Certifying That a Patent Claiming a Drug Is Invalid or Will Not Be Infringed* (68 FR 36676, at 36680 (June 18, 2003)).~~

~~continued, "we have clarified the rule to ensure that *if* the patent claims the *drug product as defined in § 314.3*, the patent must be submitted for listing. . . . The key factor is whether the patent being submitted claims the finished dosage form *of the approved drug product.*"[56]~~

~~169~~265. Section 314.3(b) defines a "drug product" as "a finished dosage form, for example, tablet, capsule, or solution, *that contains a drug substance*, generally, but not necessarily, in association with one or more other ingredients." ~~(emphasis added).~~Drug substance is then defined as the active ingredient. The active ingredient in Lantus is insulin glargine.

266. There is no open question, or room to debate, whether Sanofi's initial injector pen patents – which, as described below, do not claim insulin glargine – could be submitted for listing in the Orange Book. The statute is clear. The regulations are clear. The FDA's explanation of its regulations is clear. Even the drug companies seeking to alter existing law were clear: the law and regulations in effect did not permit the listing of the initial injector pen patents unless those patents also claimed the active ingredient insulin glargine. And (while, again, there is no "reasonableness" defense for failing to satisfy the binary first prong of the patent listing test) it would not have been reasonable for Sanofi, or another pharmaceutical company it Sanofi's position, to believe otherwise.

~~170~~267. The ~~DCA~~initial injector pen patents claim a specific form of a pen-type injector, ~~or~~ a dose indicator, drive mechanism or housing in specific forms for a pen-type injector. They neither claim insulin glargine nor claim a pen filled with insulin glargine.

268. The '833 patent has fourteen claims. All fourteen claims refer to a "pen-type injector." None claim insulin glargine, or even insulin in conjunction with the pen-type injector.

~~[56] *Id.* (emphasis added).~~

The terms "insulin" or "insulin glargine" do not appear anywhere in the '833 patent – not in the claims, the specification, or otherwise.

269. The '833 patent does not claim the active ingredient of Lantus, which is injectable insulin glargine.

270. The '297 patent has eight claims. All eight refer to a "dispensed dose indicator" as a part of a pen-type injector. None claim insulin glargine, or even insulin in conjunction with the pen-type injector. The terms "insulin" and "insulin glargine" do not appear anywhere in the '297 patent – not in the claims, the specification, or otherwise.

271. The '297 patent does not claim the active ingredient of Lantus, which is injectable insulin glargine.

272. The '864 patent has ten claims. All refer to a "drive mechanism." None of the claims in the '864 patent claim insulin glargine, or even insulin in conjunction with the pen-type injector. All are directed to a single, narrow aspect of the device – specifically the drive mechanism – and are in no way limited to drive mechanisms for use in insulin delivery devices. The term "insulin glargine" do not appear anywhere in the '864 patent – in the claims or otherwise.[97]

273. The '864 patent does not claim the active ingredient of Lantus, which is injectable insulin glargine.

274. The '044 patent has twenty claims. All twenty refer to the "housing part for a medication dispensing apparatus." None of the claims in the '044 patent claim insulin glargine, or even insulin in conjunction with the pen-type injector. The terms "insulin" and "insulin glargine" do not appear anywhere in the '044 patent – in the claims or otherwise.

[97] *See In re Lantus Direct Purchaser Antitrust Litig.*, No. 16-cv-12652-JGD, 2018 WL 355372, at *5 (D. Mass. Jan. 10, 2018) ("[T]he '864 patent itself does not mention Lantus or insulin glargine.")

275. The '044 patent does not claim the active ingredient of Lantus, which is injectable insulin glargine.

~~171.~~ ~~The DCA~~276. None of the initial injector pen patents ~~do not~~ claim a drug substance, a drug product, or a method of using a drug. The ~~DCA~~initial injector pen patents are not drug substance patents (they do not claim ~~no "~~Lantus's active ingredient~~"~~ insulin glargine), drug product patents (because they claim ~~no "~~neither the finished dosage form ~~. . . that contains a drug substance"~~of Lantus nor insulin glargine), or patents for a method of using a drug. ~~And the DCA injector pen patents do not make a claim for "the drug for which the application was submitted", i.e., Lantus in its various pen injector formulations (nor, of course, for Lantus in its vial formulation).~~

277. The initial injector pen patents fall squarely into the category of patents that cannot be submitted for listing in the Orange Book. Therefore, Sanofi improperly submitted the initial injector pen patents to the FDA for listing in the Orange Book.

~~172~~**N. ~~Therefore, the DCA injector pen patents were not eligible to be listed in the~~Sanofi rearranges its Orange Book ~~for any Lantus product~~listings to create a patent roadblock to follow- on competition.**

~~173~~278. Until the summer 2013, Sanofi had identified a single product, Lantus, available in two formulations (vial and cartridge), in the FDA's Orange Book.

~~174~~279. In or about August 2013, for the first time, Sanofi split the listing in the Orange Book to reference two products under a single NDA: Product 001 identified "Lantus" and Product 002 "Lantus SoloSTAR." Exhibit K to this complaint is the Orange Book listing for insulin glargine 34th edition (2014). ~~The Orange Book also continued to list Lantus (now Product 001) in two general formulations, "INJECTABLE" (i.e., the vial formulation), and "INJECTION" (i.e., the cartridge formulation).~~

~~175~~280. With respect to product 001, Lantus, Sanofi sent patent information to the FDA causing it to list (1) the original '722 drug substance patent, (2) the vial formulation patents, and (3) the '833 ~~DCA~~ injector pen patent.

~~176~~281. The '722 drug substance patent claimed both the vial and cartridge formulations of Lantus. But the vial formulation patents did not claim the Lantus cartridge formulation (because no polysorbate was added to the cartridges)~~, so~~. So Sanofi should not have submitted the vial formulation patents ~~should not have been listed~~for listing in the Orange Book as to the cartridge formulation. And the '833 ~~DCA~~ injector pen patent did not claim the vial formation (because the vial formulation had no injector pen)~~, so~~. So Sanofi should not have submitted the '833 ~~DCA~~ injector pen patent ~~should not have been listed~~for listing in the Orange Book as to the vial formulation.

~~177~~282. With respect to product 002, Lantus SoloSTAR, Sanofi did *not* list the vial formulation patents. Instead, Sanofi listed the original '722 drug substance patent and two ~~DCA~~ injector pen patents (the '297 and '864 patents) as claiming Lantus SoloSTAR. (Sanofi later added the other ~~DCA~~initial injector pen patents to this list).

~~178~~283. The '722 drug substance patent claimed the active ingredient in Lantus SoloSTAR. But the ~~DCA~~initial injector pen patents did not claim a drug substance, drug product, or method of using a drug product~~. They~~: they claimed packaging. So Sanofi should not have ~~been listed~~submitted these patents to the FDA for listing in the Orange Book.

284. To make clear the proper distinction, Sanofi *could* have split its original "Lantus" Orange Book listing into three products: Lantus vials (to which the original '722 formulation patent was relevant and the '652 and '930 polysorbate patents were arguably relevant); Lantus cartridges (to which the original '722 formulation patent was relevant); and SoloSTAR (to

which the original '722 formulation patent was relevant).[98] But Sanofi did not. Instead, Sanofi represented to the FDA and would-be competitors that the '930 and '652 patents covered products they did not.

~~179~~285. The only lawful listings available to Sanofi at the end of 2013 were (i) ~~that~~ the '722 patent as to Lantus ~~and Lantus SoloSTAR~~ (with expiry on August 12, 2014, and pediatric exclusivity through February 12, 2015), and (ii) ~~that~~ the vial formulation patents, as to the vial formulation of Lantus *only* (not the original 3 mL cartridge formulation with OptiClik injector pen, nor the SoloSTAR ~~disposable insulin device~~packaging).

~~180~~286. By ~~wrongfully listing~~improperly asking the FDA to list the other patents, by the end of 2013, Sanofi had created an unlawful Orange Book roadblock for would-be follow-on biologic competitors for the insulin glargine market. It had falsely and misleadingly ~~listed~~represented that the '652 and '930 vial formulation patents ~~as ostensibly claiming~~claimed the cartridge formulation of Lantus (even though Sanofi's FDA approvals did *not* provide for the addition of 20 ppm of polysorbate 20 to the 3 mL *cartridge* presentation of Lantus insulin glargine [rDNA origin] injection). And it had falsely and misleadingly ~~listed the DCA~~represented that the initial injector pen patents ~~as claiming Lantus SoloSTAR~~could be listed in the Orange Book.

287. Sanofi's maneuver did not serve the policy objectives of the Hatch-Waxman Amendments and its regulations. That law, and those regulations, were aimed at expediting the availability of affordable versions of very expensive brand name drugs. Although a hypothetical competitor *might* be subject to non-frivolous patent infringement claims for patents *other* than those claiming the active ingredient of a drug or a method of using that drug (although Lilly

[98] The initial injector pen patents should not have been submitted to the FDA for listing under *any* product.

was not, here, for the reasons discussed), those infringement claims are not meant to be tested through the Hatch-Waxman framework. A patent holder must wait until the product infringing the non-drug patents reaches the market. Then, and only then, may it file suit for patent infringement.

~~181. As a result~~288. But because of Sanofi's patent submissions, any would-be competitor seeking FDA approval to market insulin glargine (after expiration of the '722 patent in mid-February 2015) ~~a follow-on,~~in an injector pen ~~formulation of insulin glargine~~packaging would be forced to file (unnecessary) paragraph IV certifications as to the vial formulation patents and the ~~DCA~~initial injector pen patents. Any would-be competitor seeking approval to market insulin glargine in cartridges would be forced to file an unnecessary paragraph IV certifications as to the vial formulation patents and one of the initial injector pent patents, the '833 patent. And Sanofi could then sue, triggering the 30-month statutory bar on final FDA approval of the competitor's application.

~~**M. The October 2013 labeling revision.**~~

~~182. In October of 2013 the FDA approved a labeling revision for Lantus. Exhibit L hereto is a copy of the October 2013 revision of the Prescribing Information for Lantus.~~

~~183. Each milliliter of the 3 mL cartridge presentation referred to in section 11 of Exhibit L contains 100 Units (3.6378 mg) insulin glargine, 30 mcg zinc, 2.7 mg m-cresol, 20 mg glycerol 85%, and water for injection, and its pH is adjusted by addition of aqueous solutions of hydrochloric acid and sodium hydroxide.~~

~~184. The 2013 revision did not change the frivolity of Sanofi's Orange Book listings.~~

~~N~~O. **Lilly's effort to obtain approval to market insulin glargine for injection.**

1. **Lilly uses its proprietary KwikPen injector with its Humalog product.**

289. On October 5, 2006, Lilly submitted to the FDA a supplemental NDA with respect to its Humalog (insulin lispro) products, seeking permission to manufacture, market, and sell its Humalog products in "disposable (prefilled) insulin injector pens" – meaning Lilly's KwikPen.

290. Humalog and Lantus are different products – different molecules – of insulin. One is a rapid-acting insulin; the other a long-acting insulin. They have different mechanisms of action and pharmacokinetic profiles. Neither is a generic or follow-on product of the other.

291. On September 6, 2007, the FDA approved Lilly's supplemental application for Humalog, granting Lilly the right to sell Humalog in its KwikPen. Upon approval, the FDA described this new change to Lilly's Humalog products as a change to Humalog's "packaging."

292. Two months later, on November 6, 2007, the PTO issued United States Patent No. 7,291,132 ("the '132 patent"), entitled "Medication Dispensing Apparatus with Triple Screw Threads for Mechanical Advantage," based on a 2004 patent application. Lilly believed that the '132 patent covered KwikPen.

293. In or around February 2008, Lilly announced the launch of its Humalog KwikPen products.

294. At the time Lilly obtained approval for, patented, and first launched its KwikPen product (with Humalog), Sanofi did not yet own and had not yet attempted to list any of the initial injector pen patents in the Orange Book. The first initial pen patent, the '833 patent, issued several years later, in 2011.

295. Sanofi's initial injector pen patents claimed priority to a patent application filed before Lilly's KwikPen patent application. So once Sanofi obtained the first of its initial injector

pen patents in 2011, it could have sued Lilly for infringing that patent – based not on the Hatch-Waxman Amendment infringement provisions, but on ordinary principles of patent law – that Lilly was selling a product that (hypothetically) Sanofi alleged was covered by Sanofi's initial injector pen patents.

296. Had Sanofi sued once it obtained the injector pen patents, it would have been entitled to seek damages for each and every KwikPen sold in conjunction with Humalog – a blockbuster product. This meant potentially monumental damages.

297. But to sue – as with any lawsuit – Sanofi would have needed an objectively reasonable basis to claim that Lilly's product infringed its initial injector pen patents.

298. Sanofi never took the position that Lilly's KwikPen infringed Sanofi's initial injector pen patents, let alone sue Lilly for infringement.

2. Lilly files a § 505(b)(2) NDA for Basaglar.

~~185~~299. For several years, Lilly~~, one of the original leaders in insulin products worldwide,~~ worked with Boehringer Ingelheim to develop a follow-on insulin glargine product ~~having a similar safety and efficacy profile as~~like Sanofi's Lantus and Lantus SoloSTAR.

~~186~~300. Lilly filed an investigational new drug application, and worked with FDA on numerous aspects of ~~the Lilly~~its product. Among other things, Lilly had a scientific and business plan to use its KwikPen ~~platform – an injector pen device FDA approved and used successfully for other, widely-used Lilly products~~packaging for its insulin glargine product. After review, the FDA agreed that the KwikPen was a viable design for Lilly's insulin glargine ~~and several other Lilly products. In doing so, the~~. The FDA noted that KwikPen insulin products have been marketed for a number of years without significant user problems or product quality issues.

~~187~~301. In late 2013, Lilly filed with the FDA NDA No. ~~205-692~~20-5692 seeking approval to market insulin glargine [rDNA origin] for injection, 100 units/mL, in the U.S. The application was submitted under § 505(b)(2) of the FDCA~~, it could not be submitted under "biosimilar" approval pathway because Lantus had been approved under the FDCA, not the PHS.~~.[99]

~~188.~~ 302. In its application, Lilly relied ~~in its application~~ on safety and efficacy studies comparing Lantus to other human or rapid-acting insulin products~~, which~~. These studies concluded that Lantus's effect on blood glucose levels was comparable to that of human insulin. The safety and effectiveness of Lantus was compared to that of once-daily and twice-daily Basaglar in open-label, randomized, active- controlled, parallel studies of 2,327 adults and 349 pediatric patients with type 1 diabetes mellitus and 1,563 adult patients with type 2 diabetes mellitus. In general, the reduction in glycated hemoglobin (HbA1c) with Lantus was similar to that of Basaglar, meaning that Basaglar was "non-inferior" to Lantus. These studies established a "bridge" between Basaglar and Lantus to demonstrate that Basaglar was sufficiently similar to Lantus such that reliance on Lantus studies was scientifically justified. The Lantus data, together with product-specific data (including product-specific data demonstrating safety and effectiveness), established Basaglar's safety and effectiveness for its proposed uses. The composition, strength, and presentation of Basaglar were determined to be similar in composition, strength and presentation to Lantus.

~~189~~303. Basaglar did not use polysorbate, a poloxamer, or esters or ethers of polyhydric alcohols.

[99] It could not be submitted under "biosimilar" approval pathway because Lantus had been approved under the FDCA, not the PHS.

~~190~~304. Because Basaglar did not use a polysorbate, a poloxamer, or ~~esters or~~ esters or ethers of polyhydric alcohols, it did not infringe the vial formulation patents.

305. Lilly's NDA for Basaglar sought to use Lilly's KwikPen, invented, patented, and approved at least four years before the first injector pen patent for SoloSTAR. Lilly did not intend to use Sanofi's SoloSTAR pen packaging; Lilly intended to use its own proprietary, patented injector pen device.

~~191~~306. On December 18, 2013, Lilly sent a "Notice of Paragraph IV Certifications" to Sanofi, informing Sanofi that Lilly had filed an NDA pursuant to § 505(b)(2) to market the Basaglar. The notice letter addressed all patents listed in the Orange Book for Lantus and Lantus SoloSTAR. Lilly filed a paragraph III certification as to the '722 patent, agreeing to wait to market its product until that compound patent expired. It filed paragraph IV certifications as to the vial formulation patents and ~~DCA~~initial injector pen patents, certifying that those patents were invalid, unenforceable, and/or would not be infringed by the commercial manufacture, use, or sale of the Lilly NDA product.

~~192~~307. In other words, Lilly sought approval to sell its insulin glargine injector product upon the February 15, 2015 expiration of Sanofi's insulin glargine patent and its pediatric exclusivity.

~~193~~308. On December 19, 2013, Sanofi U.S. received Eli Lilly's Notice of Paragraph IV Certifications.

~~194~~309. On December 20, 2013, Sanofi GmbH received Eli Lilly's Notice of Paragraph IV Certifications.

~~195~~310. Meanwhile, Sanofi collected the additional '044 ~~DCA~~ injector pen patent, and listed it in the Orange Book.

~~196~~311. On January 23, 2014, Lilly sent an "Amended Notice of Paragraph IV Certifications," repeating its paragraph III certification as to the '722 patent, and adding the '044 patent to the list of patents that Lilly claimed were invalid, unenforceable, or would not be infringed by Basaglar.

~~197~~312. Both of Lilly's December and January submissions contained detailed statements analyzing the prosecution histories and claims of the Orange Book-listed patents and identified numerous limitations missing in Lilly's NDA product. Lilly's detailed statements warned that Lilly ~~may~~might defend any baseless lawsuits by asserting, among other things, patent misuse.

~~198~~313. On January 24, 2014, Sanofi received Eli Lilly's Amended Notice of Paragraph IV Certifications.

~~199~~314. On or about January 27, 2014, Sanofi GmbH received Eli Lilly's Amended Notice of Paragraph IV Certifications.

~~200~~315. Lilly's December notice of paragraph IV certifications was accompanied by an offer of confidential access. Lilly offered Sanofi access to confidential information contained in its NDA.

~~201~~316. On January 23, 2014, Lilly and Sanofi executed an offer for confidential access, entitled "Terms of Confidential Access."

~~202~~317. On January 25, 2014, Sanofi received approximately 66 pages of Lilly's § 505(b)(2) application. Those pages were provided subject to the agreed confidentiality and included an identification of the active and inactive ingredients of the formulation of Basaglar.

~~203~~318. Sanofi did not request any further information regarding the formulation of Basaglar, and so Lilly provided none ~~further was provided~~.

~~204~~319. The pages of Lilly's § 505(b)(2) application (i) showed the list of ingredients of Lilly's NDA product, and (2) identified the type of injector pen ~~by which the~~that Lilly ~~NDA product would be administered~~intended to use. The documents ~~showed that the Lilly NDA product would not infringe any of the claims the two injector pen patents (the '864 and '044 patents) or any claims in the two vial formulation patents (the '652 and '930 patents).~~provided no basis for a reasonable pharmaceutical company in Sanofi's position to realistically expect to succeed in proving Lilly's product infringed any properly listed, valid, and enforceable patent.

~~O~~3. ~~The~~ Sanofi waited to sue Lilly over KwikPen until its lawsuit could block competition to a Sanofi blockbuster product.

320. Again, Lilly's Basaglar KwikPen § 505(b)(2) application was not the first time Sanofi learned about Lilly's KwikPen. Lilly's KwikPen had been commercially available with Humalog since 2007.

321. As explained above, the KwikPen and the SoloSTAR were considered packaging by the FDA – and even by Sanofi itself. So disputes over those patents should not have been adjudicated through the Hatch-Waxman framework – and would not have been, absent Sanofi's anticompetitive scheme to delay Lantus competition.

322. But, again, the fact that Sanofi's initial injector pen patents did not cover the Lantus drug product (and so could not properly be listed in the Orange Book) did not mean that Sanofi was without recourse to protect its intellectual property. Drug companies can seek to vindicate non-listed patents, like a patent over packaging or a process for making a drug, through a traditional patent infringement suit, once the product launched. But such a lawsuit would not have enabled Sanofi to delay any Lilly drug from coming to the market – the thirty-month stay is unique to Hatch-Waxman suits.

323. But there were other benefits to a more traditional patent suit: because Lilly's KwikPen was already on the market, Sanofi could have sought damages for each infringing sale of a KwikPen – *if* it *actually* thought Lilly's product infringed its initial injector pen patents.

324. Instead, Sanofi did *not* sue Lilly over Lilly's sale of the KwikPen in conjunction with Humalog – either when Sanofi obtained its first injector pen patent in 2011 or at any time thereafter. The first time Sanofi claimed Lilly's KwikPen infringed the initial injector pen patents is when those allegations would – because of Sanofi's misdeeds –automatically delay Lilly's Basaglar launch for two-and-a-half years.

P. Sanofi's baseless lawsuit against Lilly.

~~205~~325. On January 30, 2014 – just three days after its receipt of Lilly's documents – Sanofi sued Lilly ~~on~~for infringing the '652 and '930 vial formulation patents~~,~~ and the '044 and '864 ~~DCA~~ injector pen patents. The action was brought in the United States District Court for the District of Delaware, bearing civil action number 14-cv-113 (the "*Sanofi I*" litigation).

~~206~~326. Sanofi ~~commenced~~filed *Sanofi I* within 45 days of receiving Lilly's notice letter. As a result – and despite the absence of any merit to the claims of infringement – Sanofi obtained an automatic 30-month stay of FDA approval of Basaglar. Absent an earlier ruling on the merits from the district court, the FDA now was statutorily barred from granting Lilly final approval for Basaglar until May 16, 2016.

~~207~~327. Sanofi alleged in its complaint that it has "listed each of the '864, '044, '652, and '930 Patents in the Orange Book as covering its Lantus and/or Lantus SoloSTAR products."

~~208~~328. That statement was misleading. In fact, the '652 and '930 vial formulation patents were only listed as claiming Lantus, and the '044 and '864 pen patents were only listed as claiming Lantus SoloSTAR.

~~209~~329. Sanofi sued Lilly with respect to the '652 vial formulation patent even though, after reviewing the materials provided by Lilly, its lawyers had no basis to conclude that ~~the formulation of~~Lilly's Basaglar ~~is covered by~~infringed any claim of the '652 patent. No reasonable pharmaceutical company in Sanofi's position would realistically expect to succeed in proving infringement.

~~210~~330. Sanofi sued Lilly with respect to the '930 vial formulation patent even though, after reviewing the materials provided by Lilly, its lawyers had no basis to conclude that ~~the formulation of~~Lilly's Basaglar ~~is covered by~~infringed any claim of the '930 patent. No reasonable pharmaceutical company in Sanofi's position would realistically expect to succeed in proving infringement.

~~211~~331. The ~~66~~sixty-six pages of documents produced by Lilly pursuant to the Terms of Confidential Access included an identification of the particular injector device that would be used with the Lilly NDA product. Sanofi did not request from Lilly more information regarding Lilly's injector device.

~~212~~332. Sanofi sued Lilly with respect to the '864 ~~DCA~~ injector pen patent even though, after reviewing the materials Lilly provided, its lawyers had no basis to conclude that Lilly's KwikPen was covered by any claim of the '864 patent. No reasonable pharmaceutical company in Sanofi's position would realistically expect to succeed in proving infringement.

333. For example, Lilly's patent over KwikPen, issued November 6, 2007, claimed

> A medication dispensing apparatus that provides a mechanical advantage. During dose preparing, a nut rotating element and a screw element are in a first axial arrangement such that a

> screwing motion of the nut rotating element and screw element relative to the apparatus housing that moves the elements a first axial distance from a home position screws a nut along a drive member threaded shaft a second axial distance different than the first axial distance. During dose dispensing, the nut rotating element and the screw element are in a second axial arrangement, whereby a screwing motion of the screw element relative to the housing back toward the home position advances a plunger in the distal direction to axially advance the nut and thereby the drive member and a fluid container piston to dispense medicine.[100]

334. The insulin-dispensing plunger is backed by a screw with a nut on the end. The nut has threading on the outside of it, which lines up with threading on the inside of the housing (tube). To fill and then empty the pen, the screw and nut rotate relative to the housing (the tube) of medication, but not relative to each other.[101]

335. The external portion of plunger of the pen claimed by Lilly's KwikPen patent does not move in a one-to-one ratio with the movement of the internal rotating nuts, so even if only a very small dose of insulin is required, the plunger can be moved an appreciable distance by the user, reducing the likelihood that a user might think she has dispensed insulin when she has not, or that she thinks no insulin was dispensed when it in fact was.

336. Lilly's KwikPen patent claimed a novel device for a number of reasons:

- It "makes easier the plunging needed to dispense medication."
- It allows for "an externally accessible plunging member that . . . travels a greater distance than the [plunger] it advances, whereby even smaller doses achieved with shorter drive member movements can involve meaningful plunging member motion."
- It is "mechanically efficient" and can be made with "less expensive component parts," and "plastic" parts instead of "metal springs," such that it is "justifiably disposable" after the insulin has been used completely.
- It has a "short axial length" and a "small diameter."

[100] US Patent No. 7,291,132, abstract.

[101] *Id.* col. 1 *l.* 61 – col. 2 *l.* 30.

- It is much simpler than other injector pens, "with a limited amount of parts and complexity."

337. In simple terms, Lilly's KwikPen patent claims – and Lilly's KwikPen employs – a single moving element that acts as a plunger and that moves relative to a single tube in the pen in order to first fill a void with the proper dose of insulin, and then to dispense that insulin dose.

1. Sanofi asserted the '864 patent, even though Lilly's KwikPen did not infringe.

338. Sanofi's '864 patent, issued nearly 6 years later on October 15, 2013, claimed a different type of medicine-dispensing mechanism: a "drive mechanism suitable for use in drug delivery devices." The term "insulin glargine" appears nowhere in the patent. The background describes the pen, without any reference to insulin or insulin glargine:

> The drive mechanism may include a housing, a dose dial sleeve, and drive sleeve. A clutch is configured to permit rotation of the drive sleeve and the dose dial sleeve with respect to the housing when the dose dial sleeve and drive sleeve are coupled through the clutch. Conversely, when the dose dial sleeve and drive sleeve are in a de-coupled state, rotation of the dose dial sleeve with respect to the housing is permitted and rotation of the drive sleeve with respect to the housing is prevented. In the de-coupled state, axial movement of the drive sleeve transfers force in a longitudinal direction for actuation of a drug delivery device.[102]

339. In other words, the introduction to the '864 patent contemplates: (a) a housing (the main tube) with a helical thread on the inside; (b) a "dose dial sleeve" with threads that match up with those on the housing; (c) a "drive sleeve" that could, at different times, be paired with the dose dial sleeve or not; (d) a "clutch" that paired and unpaired the two sleeves; and, preferably, (e) a piston rod. When the dose dial sleeve and the drive sleeve are paired, they rotate together, relative to the housing. When the two sleeves are not paired, the dose dial

[102] U.S. Patent No. 8,556,864 abstract.

sleeve still rotates relative to the housing, but the drive sleeve does not, and compressing the piston rod pushes the drive sleeve towards the needle of the pen like a plunger.[103]

340. The "Technical Specification" section explains that the '864 patent "relates to drive mechanisms suitable for use in drug delivery devices . . . ."[104]

341. But neither the background section nor the technical specification section of the '864 patent dictate, on their own, what the patent "claims." The '864 patent has ten "claims," some dependent and some independent, all of which claim a "drive mechanism." None claim insulin glargine, or a pen containing a "drive mechanism" and insulin glargine.

342. Sanofi's '864 patent discloses a different utility for its invention than those claimed by Lilly with regard to Lilly's KwikPen. The inventors wrote, "[s]urprisingly, it was found that the drive mechanism according to instant invention without having a unidirectional coupling provides a valuable technical alternative for drive mechanisms, wherein reduced force is needed to actuate the mechanism."[105]

343. In other words, Sanofi's SoloSTAR patent claims – and Sanofi's SoloSTAR pen employs – two different moving parts that sometimes move in tandem (and sometimes do not) relative to the housing to create and fill a void with the required dose of insulin, then dispense it.

2. Sanofi's allegations and Lilly's response.

~~213~~344. Sanofi also sued Lilly with respect to the '044 ~~DCA~~ injector pen patent, even though, after reviewing the materials Lilly provided, its lawyers had no basis to conclude that Lilly's KwikPen was covered by any claim of the '044 patent. No reasonable

[103] *Id.* col 2, *ll.* 6-27.

[104] *Id.* col. 1, *ll.* 18-23.

[105] *Id.* col. 1 *ll.* 62-66.

pharmaceutical company in Sanofi's position would realistically expect to succeed in proving infringement.

~~214~~345. At the time that Sanofi brought suit against Lilly, it acknowledged its market power over Lantus and its generic and follow-on versions. It pleaded that there were "[c]urrently . . . no generic or follow-on versions of Lantus or of Lantus SoloSTAR approved by the [FDA] for sale in the United States."

~~215~~346. Sanofi claimed that a launch of Lilly's Basaglar would cause Sanofi "irreparable harm for which they have no adequate remedy at law." Sanofi sought to have Lilly enjoined "from engaging in any commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of the insulin glargine [rDNA origin] injection in a prefilled insulin delivery device, 100 units/mL as claimed by the Patents-in-Suit for the full terms thereof (and any additional period of exclusivity to which Plaintiffs and/or the Patents-in-Suit are, or become, entitled), and from inducing or contributing to such activities."

~~216~~347. Sanofi immediately capitalized on its frivolous lawsuit – its stock soared. News of the lawsuit received great attention in the market. One analyst reported that the 30-month delay in Basaglar availability "would raise Sanofi's earnings per share from 2015 through 2020 by about 6 percent and reduce Lilly's EPS for the period by about 2 percent."~~37~~106

~~37~~106 Analysts observed that another purpose in Sanofi's delaying Lilly's approval was to allow Sanofi to attempt to transition the insulin glargine market to a different Sanofi insulin product, code-named U300. Sanofi had stated that U300 would not be submitted for FDA approval until at least the second quarter of 2014, which meant that Sanofi would not likely receive approval from the FDA until after February 2015, when Sanofi's '722 patent exclusivity for insulin glargine would expire. But if it could delay competition in the insulin glargine market beyond February 2015, it could obtain approval for its new U300 product and move purchases of insulin glargine to the new product before any competitor – including Lilly – could cut into its monopoly.

~~217~~348. On February 19, 2014, Lilly answered the complaint. It denied the charges of infringement. It asserted affirmative defenses of patent misuse and prosecution laches. It counterclaimed, seeking declarations of non-infringement, invalidity, and non-enforceability of the patents for patent misuse and prosecution laches. And ~~it alleged~~, alleging the '864 and '044 patents were improperly listed in the Orange Book~~;~~ pursuant to 21 U.S.C. § 355(c)(3)(D)(ii)(I), Lilly sought an order requiring Sanofi to delist the '864 and '044 patents from the Orange Book.

349. Lilly denied all allegations that its proposed Basaglar KwikPen product would infringe Sanofi's initial injector pen patents or vial formulation patents. It explained that it provided Sanofi with its basis for claiming not infringed in its paragraph IV notice. And it raised an affirmative defense, and sought declaratory judgments, that its product would *not* infringe Sanofi's patents.

~~218~~350. Lilly expressly pleaded the anticompetitive effect of Sanofi's lawsuit:

> Sanofi is aware that no claim of the patents-in-suit covers [Basaglar]. For example, before this action was filed, Lilly provided Sanofi with notice that the patents-in-suit do not cover [Basaglar], including reasons for why the claims of the patents-in-suit would not be infringed, and provided Sanofi's counsel with copies of documents identifying the formulation of [Basaglar] and a device by which it may be injected. Despite the information provided, Sanofi filed the present action with no reasonable bases for doing so. In maintaining this action, *Sanofi is attempting to extend the scope of the patents-in-suit with intended anticompetitive effects*. Accordingly, for at least these reasons, the patents-in-suit are unenforceable for patent misuse.

~~219~~351. Lilly also alleged anticompetitive harm "[b]y reason of Sanofi's baseless litigation and/or attempt to expand the scope of the patents-in-suit, *with consequent harm to Lilly and other members of the public.*"

~~220~~352. Lilly further alleged that "Sanofi's lawsuit triggered a 30-month stay that precludes Lilly from entering the market beyond February 2015 when the '722 patent exclusivity expires – a concrete harm to Lilly and the public that is the direct result of Sanofi's alleged anticompetitive conduct." Lilly further argued to the district court that anticompetitive harm existed due to "Lilly's intention to enter the market" and its "preparedness to do so, both of which are evidenced by Lilly's NDA, a significant filing demonstrating (1) actual and affirmative steps toward entering the market, and (2) Lilly's background, experience, and financial capability to enter."

353. On March 17, 2014, Sanofi moved to dismiss Lilly's patent misuse and invalidity counterclaims[107] (the court later denied that motion, explaining Sanofi's conduct "touched on all the elements" of patent misuse and "there [was] a factual basis for" Lilly's claim). Sanofi did *not* challenge Lilly's Orange Book delisting counterclaim.

~~221~~354. On March 25, 2014, the PTO issued United States Patent No. 8,679,069 ("the '069 patent"), entitled "Pen-Type Injector." It expires April 12, 2025. A true and correct copy of the '069 patent is attached as Exhibit M to this complaint. The '069 patent is yet another in the string of ~~DCA~~initial injector pen patents. ~~After acquiring its rights to the patent,~~ Sanofi listed the '069 patent in the Orange Book as claiming product 002, Lantus SoloSTAR. The listing of the '069 patent was unlawful for all the same reasons as the other ~~DCA~~ injector pen patent listings.

~~222~~355. On May 14, 2014, Lilly sent a Sanofi a paragraph IV certification as to the '069 ~~DCA~~ injector pen patent, disclosing that Lilly had amended its paragraph IV certifications in its Basaglar NDA to include the '069 patent. In its letter, Lilly stated that its

[107] The details of Lilly's allegations that one or more of Sanofi's patents was invalid are currently under seal in the underlying litigation.

certification to FDA alleges, *inter alia*, that the '069 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Lilly's NDA product.

~~223~~356. After receipt of Lilly's May certification, Sanofi amended its complaint in *Sanofi I* to assert infringement of the '069 patent. Lilly responded, repeating the similar denials, defenses, and counterclaims as it had previously asserted (but now also applicable to the '069 patent). Again, Sanofi did not seek dismissal of Lilly's incorrect-listing counterclaim.

357. Throughout the discovery process that followed – which would have erased any doubt that no reasonable pharmaceutical company would have any objectively realistic expectation of success – Sanofi maintained its sham lawsuit.

~~P~~Q. Sanofi lacked any realistic likelihood of prevailing on the merits of *Sanofi I*.

~~224~~358. A reasonable pharmaceutical company in Sanofi's position would not have ~~reasonably~~realistically expected to prevail in showing that Lilly's Basaglar infringed the '652 vial formulation patent.

~~225~~359. The '652 vial formulation patent claimed the addition of polysorbate 20, polysorbate 80, or a poloxamer to an insulin glargine solution. If an insulin glargine product did not contain one of these molecules, it did not infringe the '652 patent. A reasonable pharmaceutical company would know that. Sanofi knew that.

~~226~~360. Lilly's Basaglar did not contain polysorbate 20, polysorbate 80, or a poloxamer. A reasonable pharmaceutical company that had received the portions of Lilly's § 505(b)(2) application it provided to Sanofi would know that. Sanofi knew that.

~~227~~361. Because the '652 vial formulation patent covered only insulin glargine products containing polysorbate 20, polysorbate 80, or a poloxamer, and Lilly's Basaglar did not contain polysorbate 20, polysorbate 80, or a poloxamer, no reasonable pharmaceutical

company would have expected to prevail on the merits of a claim that Lilly's Basaglar infringed the '652 vial formulation patent.

~~228~~362. The '930 vial formulation patent claimed the addition of polysorbate 20, polysorbate 80, a poloxamer, or an ester or ether of polyhydric alcohol to an insulin glargine solution. If an insulin glargine product did not contain one of these molecules, it did not infringe the '930 patent. A reasonable pharmaceutical company would know that. Sanofi knew that.

~~229~~363. Lilly's Basaglar did not contain polysorbate 20, polysorbate 80, a poloxamer, or an ester or ether of polyhydric alcohol to an insulin glargine solution. A reasonable pharmaceutical company that had received the portions of Lilly's § 505(b)(2) application it provided to Sanofi would know that. Sanofi knew that.

~~230~~364. Because the '930 vial formulation patent covered only products containing polysorbate 20, polysorbate 80, a poloxamer, or an ester or ether of polyhydric alcohol, and Lilly's Basaglar did not contain polysorbate 20, polysorbate 80, a poloxamer, or an ester or ether of polyhydric alcohol, no reasonable pharmaceutical company would have expected to prevail on the merits of a claim that Lilly's Basaglar infringed the '930 vial formulation patent.

~~231~~365. The ~~DCA~~ injector pen patents claimed only a specific type of injector pen – ~~that used in Lantus~~like SoloSTAR – or aspects or mechanisms of that particular pen. If a different pen were used – a pen that did not encompass the aspects or mechanisms covered by the ~~DCA~~ injector pen patents, that injector pen would not infringe the ~~DCA~~ injector pen patents. A reasonable pharmaceutical company would know this. Sanofi knew this.

~~232~~366. Lilly's KwikPen, which it disclosed it would use in conjunction with Basaglar, was different from the pen described in ~~the~~ DCAoriginal injector pen patents. A reasonable pharmaceutical company would know this. Sanofi knew this.

~~233~~367. Because the ~~DCA~~initial injector ~~pens~~pen patents covered only certain types of pens (or aspects or mechanisms of those pens), and Lilly's KwikPen did not fall within that category of pens (and contained none of the aspects or mechanisms of those pens), no reasonable pharmaceutical company would have expected to prevail on the merits of a claim that Lilly's Basaglar (with its KwikPen) infringed the ~~DCA~~initial injector pen patents.

~~234~~368. Furthermore, a reasonable pharmaceutical company would have known that the ~~DCA~~initial injector pen patents did not cover a drug substance, drug product, or method of using a drug. Accordingly, a reasonable pharmaceutical company would have known that ~~it~~Sanofi was not entitled to a 30-month stay of FDA approval under the Hatch-Waxman Amendments, simply by filing a suit over the ~~DCA~~initial injector pens.

~~235~~369. The formulation of Lantus disclosed in the '722 patent would enter the public domain in February 2015. If Sanofi's asserted vial formulation patents were construed as covering the Lantus formulation disclosed in the '722 patent, then the '722 patent disclosure would render the vial formulation patents invalid.

~~Q~~R. Lilly receives tentative FDA approval for its NDA product.

~~236~~370. In August 2014, the FDA granted tentative approval for Basaglar. Time to tentative approval was quick, coming exactly ten months after the application had been filed.

~~237~~371. Basaglar did not then receive final approval due to the *Sanofi I* ~~Hatch-Waxman~~Hatch- Waxman litigation. Were it not for Sanofi's ~~wrongful~~incorrect Orange Book ~~listings~~submissions, or Sanofi's filing of the frivolous patent litigation, the FDA would have

granted Lilly final approval for Basaglar as soon as the '722 patent's pediatric exclusivity expired in February 2015. And with final FDA approval for Basaglar, Lilly would have launched Basaglar at prices discounted from those of the Lantus products upon, or reasonably soon after, final approval.

~~238~~372. Instead, Lilly was required to press on defending Sanofi's objectively meritless lawsuit. The parties engaged in substantial discovery, including interrogatories and document requests; subpoenaed non-parties; fought multiple discovery disputes; tendered experts and submitted and *Daubert* motions opposing those experts; and undertook the nuanced and complex process of claim construction. Claim construction focused on issues like, for example, what constituted a polysorbate, and what constituted an ester or ether of a polyhydric alcohol, but did not reach the fact that Lilly's Basaglar contained no polysorbate, or ester or ether of polyhydric alcohol; regardless of definition.

~~239~~373. The litigation stretched through the remainder of 2014 and all the way until September 2015. For Sanofi, every day beyond February 15, 2015 that the litigation proceeded was a win. It meant another day on which a competing insulin glargine product could be kept off the market.

~~240~~374. But its delay tactics could only last so long. The *Sanofi I* court held a final pre- trial conference on September 18, 2015, and set trial for September 28, 2015. The meritless nature of Sanofi's claims would soon be laid bare.

~~R~~S. The Sanofi-Lilly settlement.

~~241~~375. On September 28, 2015, the morning trial was set to begin, Lilly announced it had entered into a settlement agreement to resolve the patent litigation with Sanofi regarding Basaglar. As a part of the agreement, Lilly and its alliance partner, Boehringer

Ingelheim, would have the ability to launch Basaglar in the U.S. on December 15, 2016 – twenty-two months after the insulin glargine patent expired. The announcement stated that "[u]nder the terms of the agreement, Sanofi has granted Lilly a royalty-bearing license so Lilly can manufacture and sell Basaglar in the KwikPen device globally" but "details regarding the settlement [would remain] confidential." The announcement acknowledged that the FDA had "tentatively approved Basaglar [back] in August 2014" and that with the final "resolution, Lilly plans to request final approval of Basaglar from the FDA."

~~242~~376. On September 28, 2015, the *Sanofi I* court signed and entered a Consent Judgment. ~~In it, Sanofi finally admitted that Lilly's Basaglar did not infringe the vial formulation patents or DCA injector pen patents.~~ And, even though the consent judgment memorialized Lilly's agreement to stall its Basaglar launch until December 15, 2016, the ~~judgement~~judgment provided the FDA with authority to grant final approval to Lilly's Basaglar NDA.

~~243~~377. On October 16, 2015 Lilly advised the FDA of the consent ~~decree~~judgment and noted to the FDA that the ~~consent decree~~judgment stated: "This Consent Judgment constitutes a 'consent decree' pursuant to 21 U.S.C. § 355(c)(3)(C)(i)(II), such that Final Approval of Eli Lilly's NDA No. 205- 692 under 21 U.S.C. § 355(b)(2) may be granted on the date that this Consent Judgment is entered by the Court."

~~S~~T. Lilly gets final FDA approval, but must wait due to the Sanofi-Lilly agreement.

~~244~~378. On December 16, 2015, the FDA granted final approval to Lilly's Basaglar.

The approval blessed the product that Lilly had filed an NDA for in 2013, and advised Sanofi about in its 2013 and 2014 paragraph IV certifications (and that was shown in the 66 pages of confidential documents provided by Lilly to Sanofi in January of 2014).

~~245~~379. Basaglar is a clear, colorless, sterile solution for injection: 100 units per mL (U-100) in a 3 mL prefilled ~~delivery device~~package (BASAGLAR KwikPen).

~~246~~380. In approving Basaglar, the FDA noted that Lilly could not use the term "biosimilar" to compare Basaglar to Lantus, because Lantus had not been licensed under the PHS. Nevertheless, the FDA's approval under § 505(b)(2) meant that Basaglar was sufficiently similar to Lantus that data demonstrating Lantus's safety and efficacy also demonstrated Basaglar's safety and efficacy. Both contained the same molecular active ingredient – insulin glargine. Both acted in the human body in the same way. Basaglar was biologically similar to Lantus, even if it could not be called a "biosimilar."

~~247~~381. Ordinarily, a company may launch its drug as soon as it obtains final approval. But, despite receiving final FDA approval on December 16, *2015*, Lilly was forced by its agreement with Sanofi to wait exactly a full year – until December 15, *2016* – to launch Basaglar. By filing an objectively baseless lawsuit, seeking to enforce patents for which there was no reasonable, objective expectation of success, Sanofi was able to leverage a settlement delaying the launch of Basaglar.

~~248~~382. And it gets worse. Were it not for Sanofi's wrongful conduct, Lilly could have launched Basaglar even sooner, in February of 2015 – when the molecule patent expired. But for Sanofi's ~~wrongful~~incorrect listing of the vial formulation patents and ~~DCA~~initial injector pen patents in the Orange Book as covering Sanofi's Lantus cartridge formulation and Lantus SoloSTAR, it never could have sued Lilly for patent infringement under the Hatch-

Waxman Amendments in the first place. It would not have been able to obtain and automatic 30-month stay in FDA approval of Basaglar.

~~249~~383. Instead, Sanofi would have had to proceed under ordinary patent infringement law, which does not automatically enjoin the sale of a competing product. Lilly could have entered the insulin glargine market on February 16, 2015, unless Sanofi obtained a preliminary injunction preventing entry. To obtain a preliminary injunction, Sanofi would have had to demonstrate a likelihood of succession the merits of its claim. But, as explained above, there was no objectively reasonable expectation of success on the merits. So Sanofi could not have enjoined Basaglar's launch beyond February 15, 2015.

384. Although Sanofi may have been successful in delaying competition to its Lantus product, it did not succeed on the merits of its sham litigation against Lilly: instead, it settled to avoid potential findings that its patents were invalid, or not infringed, by Lilly's Basaglar.

~~250~~385. In all, Sanofi's unlawful Orange Book listing and ~~sham~~ patent infringement litigation stalled the availability of follow-on insulin glargine products for 20 months. For a drug with gross sales exceeding $7 billion a year, that translates into an additional $11.7 billion (gross) in monopoly sales Sanofi was able to reap as a result of its scheme. And all the while, purchasers were forced to pay Sanofi's supra-competitive prices.

U. Sanofi continues to buy, list, and enforce pen patents with the intent to stifle competition.

386. The Sanofi-Lilly settlement accomplished another, critical, objective for Sanofi. Recall that Lilly had filed a counterclaim against Sanofi, arguing that Sanofi's patents were improperly listed in the Orange Book. For the reasons described above, if Sanofi's sham litigation against Lilly had continued, Sanofi would have lost – and that loss could have forced Sanofi to delist its vial formulation patents and initial injector pen patents. With those patents

delisted, Sanofi would run out of patent protection for its blockbuster Lantus products (because the patent claiming the insulin glargine molecule expired in February 2015).

387. But in the consent judgment entered pursuant to the settlement agreement, the parties agreed that "all other claims and counterclaims – including Lilly's delisting counterclaim – "are dismissed with prejudice."

388. Avoidance of that delisting claim – which could have resulted in a declaratory judgment that Sanofi's pen patents could not be listed in the Orange Book – would prove important in the coming years, as Sanofi continued its scheme to block generic competition.

1. Sanofi obtained thirteen more injector pen patents and listed them in the Orange Book.

389. Even after Sanofi's litigation with Lilly, it expected other companies would soon seek to create affordable follow-on insulin glargine products. To further frustrate those efforts, Sanofi obtained and then listed in the Orange Book an additional *thirteen* patents over its SoloSTAR injector pen.

390. On March 31, 2015, the PTO issued United States Patent No. 8,992,486, ("the '486 patent"), entitled "Pen-Type Injector." The '486 patent expires June 5, 2024. Sanofi listed the '486 patent in the Orange Book on March 9, 2015, contending the patent claimed the Lantus drug product.

391. On April 21, 2015, the PTO issued United States Patent No. 9,011,391, ("the '391 patent"), entitled "Pen-Type Injector." The '391 patent expires March 26, 2024. Sanofi listed the '391 patent in the Orange Book on May 1, 2015, claiming the patent covered the Lantus drug product and a method of using the drug product.

392. On January 12, 2016, the PTO issued United States Patent No. 9,233,211 ("the '211 patent"), entitled "Relating to a Pen-Type Injector." The '211 patent expires March 2,

2024. Sanofi listed the '211 patent in the Orange Book on January 13, 2016, claiming the patent covered the Lantus drug product.

393. On August 9, 2016, the PTO issued United States Patent No. 9,408,979 ("the '979 patent"), entitled "Pen-Type Injector." The '979 patent expires March 2, 2024. Sanofi listed the '979 patent in the Orange Book on September 15, 2016, claiming the patent covered the Lantus drug product.

394. On December 27, 2016, the PTO issued United States Patent No. 9,526,844 ("the '844 patent"), entitled "Pen-Type Injector." The '844 patent expires on March 2, 2024. Sanofi listed the '844 patent in the Orange Book on December 27, 2016, claiming the patent covered the Lantus drug product.

395. On January 3, 2017, the PTO issued United States Patent No. 9,533,105 ("the '105 patent"), entitled "Drive Mechanisms Suitable for Use in Drug Delivery Devices." The '105 patent expires August 17, 2024. Sanofi listed the '105 patent in the Orange Book on January 3, 2017, claiming the patent covered the Lantus drug product.

396. On February 7, 2017, the PTO issued United States Patent No. 9,561,331 ("the '331 patent"), entitled "Drive Mechanisms Suitable for Use in Drug Delivery Devices." The '331 patent expires August 28, 2024. Sanofi listed it in the Orange Book on February 7, 2017, claiming the patent covered the Lantus drug product.

397. On March 28, 2017, the PTO issued United States Patent No. 9,604,008 ("the '008 patent"), entitled "Drive Mechanisms Suitable for Use in Drug Delivery Devices." The '008 patent expires March 2, 2024. Sanofi listed the '008 patent in the Orange Book on March 28, 2017, claiming the patent covered the Lantus drug product.

398. On March 28, 2017, the PTO also issued United States Patent Not. 9,604,009 ("the '009 patent"), entitled "Drive Mechanisms Suitable for Use in Drug Delivery Devices." The '009 patent expires August 18, 2024. Sanofi listed the '009 patent in the Orange Book on March 28, 2017, claiming the patent covered the Lantus drug product.

399. On April 4, 2017, the PTO issued United States Patent Not. 9,610,409 ("the '409 patent"), entitled "Drive Mechanisms Suitable for Use in Drug Delivery Devices." The '409 patent expires March 2, 2024. Sanofi listed the '409 patent in the Orange Book on April 4, 2017, claiming the patent covered the Lantus drug product.

400. On April 18, 2017, the PTO issued United States Patent No. 9,623,189 ("the '189 patent"), entitled "Relating to Drive Mechanisms Suitable for Use in Drug Delivery Devices." The '189 patent expires August 19, 2024. Sanofi listed the patent in the Orange Book on April 18, 2017, claiming the patent covered the Lantus drug product.

401. On October 3, 2017, the PTO issued United States Patent No. 9,775,954 ("the '954 patent"), entitled "Pen-Type Injector." The '954 patent expires March 2, 2024. Sanofi listed the '954 patent in the Orange Book on October 3, 2017, claiming the patent covered the Lantus drug product.

402. On November 28, 2017, the PTO issued United States Patent No. 9,827,379 ("the '379 patent"), entitled "Drive Mechanisms Suitable for Use in Drug Delivery Devices." The '379 patent expires March 2, 2024. Sanofi listed the '379 patent in the Orange Book on November 28, 2017, claiming the patent covered the Lantus drug product and a method of using that drug product.

403. None of the new patents claim insulin or insulin glargine. Each claims one or more aspects of the SoloSTAR packaging. All are improperly listed in the Orange Book and serve to frustrate competition.

2. Sanofi continues to sue its would-be competitors over its inappropriately listed patents.

404. Although Lilly launched Basaglar on December 15, 2016, Basaglar was – and remains – the only follow-on insulin glargine on the market. As described above, the largest drop in brand drug sales – and the largest increase in savings to the public – occurs when there are at least two follow-on competitors in the market. So although Sanofi took a hit from the market entry of Basaglar, the threat to Lantus franchise was far from over. Sanofi's additional lawsuits asserting patents that are improperly listed in the Orange Book further evinces its motive to impede competition in the market for insulin glargine.

a. Sanofi tried to block follow-on competition from Merck.

405. On May 31, 2016, Merck submitted an NDA pursuant to § 505(b)(2), seeking permission to manufacture, market, and sell a third version of insulin glargine, which it proposed to call Lusduna.

406. By the time Merck sought to manufacture its follow-on insulin glargine product, the patent covering Sanofi's original insulin glargine had expired. The patents then listed in the Orange Book included:

- The two vial formulation patents covering the addition of polysorbate as a preservative: the '652 patent and the '930 patent;
- The '833 injector pen patent, which Sanofi listed in the Orange Book as covering Lantus vials and cartridges, but not Lantus SoloSTAR;
- The other DCA injector pen patents Sanofi had asserted against Lilly: the '297 patent, the '864 patent, the '044 patent, and the '069 patent;

- And several new injector pen patents: the '486 patent, the '391 patent, and the '211 patent.

407. Merck's NDA included a paragraph IV certification to the laundry list of patents then listed in the Orange Book as covering Lantus and Lantus SoloSTAR, on August 4, 2016.

408. On August 4, 2016, Merck sent a letter notifying Sanofi of its paragraph IV certifications. Merck's letter was accompanied by an offer of confidential access to portions of Merck's application, provided that Sanofi treat the materials as if "a protective order [had] been issued."

409. Sanofi received the notice in Germany on August 8, 2016, and in New Jersey on August 9, 2016.

410. Sanofi called Merck's request that the offered portions of Merck's NDA as confidential an "onerous and unreasonable restriction[]" and refused to accept or review portions of Merck's NDA to determine if it had a viable, non-frivolous claim of patent infringement.

411. Instead, on September 16, 2016, Sanofi sued Merck on every one of these ten patents in the United States District Court for the District of Delaware. The case was assigned Civil Action No. 16-cv-812.

412. There was still no basis for Sanofi to list in the Orange Book the injector pen patents at all, or the vial formulation patents as to Lantus in either cartridges or SoloSTAR. But because Sanofi filed suit within 45 days of receiving Merck's paragraph IV certification letter, the FDA was automatically prohibited from approving Merck's product for 30 months, or until February 4, 2019.

413. After filing suit, Sanofi obtained the '844 and '105 patents, and submitted the patents for listing in the Orange Book.

414. It also obtained three more patents: U.S. Patent No. 9,457,152 ("the '152 patent"), entitled "Drive Mechanism for a Medication Delivery Device and Medication Delivery Device," issued October 4, 2006; U.S. Patent No. 9,486,587 ("the '587 patent"), entitled "Assembly for a Drug Delivery Device and Drug Delivery Device," issued November 8, 2016; and United States Patent No. 9,592,348 ("the '348 patent"), entitled "Assembly for a Drug Delivery Device and Drug Delivery Device," issued March 14, 2017.

415. Sanofi did *not* submit the '152, '587, or '348 patents for listing in the Orange Book.

416. On or around February 21, 2017, Merck amended its insulin glargine NDA. On the same day, Merck sent Sanofi and second paragraph IV notice as to the '844 and '105 patents.

417. Sanofi received the amended paragraph IV notice on February 27, 2017.

418. On March 5, 2017, Sanofi filed an amended complaint in the pending patent litigation. Its amended complaint *dropped* infringement claims as to some of the originally-asserted patents – the '833, '297, '864, '391, and '211 patents. But it *added* infringement claims as to the '105 and '844 patents, as well as the three patents (the '152, '587, and '348 patents) that Sanofi had *not* submitted for listing in the Orange Book.

419. After filing its amended complaint, Sanofi submitted its '008 patent for listing in the Orange Book. It also obtained another patent – U.S. Patent No. 9,592,348 ("the '348 patent"), entitled "Assembly for a Drug Delivery Device and Drug Delivery Device." Sanofi did not submit the '348 patent for listing in the Orange Book.

420. On May 23, 2017, Merck sent the FDA another amendment to its insulin glargine NDA. Its further amended NDA included a paragraph IV certification as to the '008 patent. Merck sent Sanofi another paragraph IV notification.

421. On June 26, 2017, Sanofi moved for leave to file a second amended complaint. Sanofi's second amended complaint omitted the '044 patent infringement claims asserted in its original and first-amended complaints. It added infringement claims as to the '008 and '348 patents. Leave to file the amended complaint was granted, and Sanofi filed its second amended complaint on June 28, 2017.

422. On July 19, 2017, the FDA granted Merck's Lusduna tentative approval. The FDA wrote that, because Sanofi "ha[d] initiated a patent infringement suit against [Merck] with respect to patent 7,918,833, 8,512,297, 8,556,864, 8,603,044, 8,992,486, 8,679,069, 9,011,391,9,233,211, [and] 7,476,652," "final approval cannot be granted until . . . expiration of the 30-month period provided for" by statute or a final judgment in Merck's favor.

423. Because Sanofi sued, it triggered a 30-month stay. Accordingly, Merck would not be able to launch its follow-on insulin glargine product until March 2019, unless it could sooner prevail in showing that Sanofi's patents were invalid or would not be infringed by Merck's proposed product before then.

424. In the meantime, Merck would have to wait. And because, as explained above, the largest drop in product price occurs when the number of follow-on products in the market goes from one to two, drug purchasers would have to wait for even more affordable insulin glargine prices, too.

b. Mylan challenges the vial formulation patents before the PTAB.

425. Merck was not the only other company looking to launch a follow-on insulin glargine product: Mylan Pharmaceuticals, Inc. was, too. By June 2017, Sanofi had added even more patents to its regulatory roadblock. The listing under Lantus in the Orange Book included:

- The two vial formulation patents covering the addition of polysorbate as a preservative: the '652 patent and the '930 patent;
- The '833 injector pen patent, which Sanofi listed in the Orange Book as covering Lantus vials and cartridges, but not Lantus SoloSTAR;
- The other initial injector pen patents Sanofi had asserted against Lilly: the '297 patent, the '864 patent, the '044 patent, and the '069 patent;
- And several new injector pen patents: the '486 patent, the '391 patent, the '211 patent, the '979 patent, the '844 patent, the '105 patent, the '331 patent, the '008 patent, the '009 patent, the '409 patent, and the '189 patent.

426. But rather than wait for Sanofi to sue Mylan and block competition, Mylan brought the fight to Sanofi.

427. On June 5, 2017, Mylan filed with the Patent Trials and Appeals Board ("PTAB") petitions for inter partes review ("IPR") of Sanofi's vial formulation patents – the '652 patent and the '930 patent. Mylan argued that the two patents were invalid because they were obvious over the prior art existing at the time Sanofi sought those vial formulation patents. As Mylan explained, Lantus's label itself (as it existed in 2000), and Lantus's label in combination with other articles, made the inventions claimed in the vial formulation patents obvious to a person having ordinary skill in the art of pharmaceutical formulation.[108] Under any of these

[108] *See* Petition for *Inter Partes* Review, *Mylan Pharms. Inc. v. Sanofi-Aventis Deutschland GmbH*, PTAB Case No. IPR2017-01526 (filed June 5, 2017) ("'652 IPR docket"); Petition for *Inter Partes* Review, PTAB Case No. IPR2017-01528 (filed June 5, 2017) ("'930 IPR docket").

several different combinations of prior art references, Mylan contended, the use of polysorbate 20, polysorbate 80, polysorbate[s] or poloxamers was obvious:

- The Lantus Label[109] and an article by Lougheed;[110]
- The Lantus Label and a Swedish article by Farmaceutiska Specialiteter I Sverige ("FASS");[111]
- The Lantus Label and an article by Grau;[112]
- An article by Owens[113] and the Lougheed article;
- The Owens article and the FASS article; and
- The Owens article and the Grau article.[114]

428. Sanofi opposed the petitions, but on December 13, 2017, the PTAB granted Mylan's petitions – meaning Mylan had demonstrated a "reasonable likelihood of success" in showing at least one claim of each patent would be found invalid – and instituted an *inter partes* review of the vial formulation patents.[115]

429. The PTAB observed that the specification of the '652 patent described insulin glargine as "a known modified insulin with a prolonged duration of action injected once daily as an acidic, clear solution that 'precipitates on account of its solution properties in the

[109] Physicians' Desk Reference, Lantus entry 709–713 (55th ed. 2001).

[110] W.D. Lougheed et al., *Physical Stability of Insulin Formulations*, 32 DIABETES 424-32 (1983).

[111] Farmaceutiska Specialiteter I Sverige ("FASS"), *Summary of Product Characteristics Entry for Insuman Infusat* (2000).

[112] Ulrich Grau & Christopher D. Saudek, *Stable Insulin Preparation for Implanted Insulin Pumps – Laboratory & Animal Trials*, 36 DIABETES 1453–59 (1987).

[113] David R. Owens et al., *Pharmacokinetics of 125I-Labeled Insulin Glargine (HOE 901) in Healthy Men – Comparison with NPH insulin and the influence of different subcutaneous injection sites*, 23 Diabetes Care 813-19 (2000).

[114] *See, e.g.*, Petition at 4, '652 IPR docket. Because the same arguments were made, and ultimately credited, in the '652 IPR docket and the '930 IPR docket, citations herein are to the '652 docket only, unless otherwise noted.

[115] The PTAB cannot instate an IPR review "unless . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314(a).

physiological pH range of the subcutaneous tissue as a stable hexamer associate."[116] The PTAB further noted that the '652 patent specification "explains that, at acidic pH, insulins exhibit decreased stability and increased susceptibility to aggregation . . . resulting in turbidity and precipitation" – in other words, insulin glargine was susceptible to falling out of its solution form "during use or shaking of the insulin solution."[117] Although the specification of the '652 patent said that Sanofi "surprisingly [] found" that adding surfactants – like "polysorbate 20," "polysorbate 80," "polysorbate[s]" or "poloxamers" – "can greatly increase the stability of acidic insulin preparations," the PTAB found that Mylan had demonstrated this was not "surprising" at all, based on what Sanofi knew when the patent application was submitted.

c. Sanofi intended to block follow-on competition from Mylan.

430. Meanwhile, Mylan submitted a § 505(b)(2) NDA in or around August or September 2017, seeking permission to manufacture, market, and sell a follow-on version of Lantus SoloSTAR. Contained within its application was a paragraph IV certification that the plethora of vial formulation patents and injector pen patents listed under Lantus in the Orange Book were invalid, unenforceable, or would not be infringed by Mylan's proposed follow-on insulin glargine product.

431. On September 15, 2017, Mylan sent a letter notifying Sanofi it had filed an NDA containing paragraph IV certifications and explaining its positions. Mylan's letter was accompanied by an offer of confidential access to portions of Mylan's application, provided that Sanofi treat the materials as if "a protective order [had] been issued."

432. On September 18, 2017, Sanofi received Mylan's paragraph IV notice letter.

[116] Decision, '652 IPR docket, at 3.

[117] *Id.*

433. Sanofi called Mylan's request that the offered portions of Merck's NDA as confidential an "onerous and unreasonable restriction[]" and refused to accept or review portions of Mylan's NDA to determine whether it had any viable, non-frivolous claim of infringement against Mylan.

434. Instead, Sanofi sued Mylan on October 24, 2017, alleging that Mylan infringed every one of Sanofi's eighteen injector pen patents and vial formulation patents.

435. Even though there was no basis for listing the vial formulation patents as protecting Lantus in a SoloSTAR or cartridge package, and although there was no basis for listing the injector pen patents in the Orange Book (because they did not claim insulin glargine) Sanofi filed suit. Because it did so within 45 days of receiving Mylan's paragraph IV certification letter, the FDA was automatically prohibited from approving Mylan's product for 30 months, or until March 18, 2020.

V. Sanofi concedes that KwikPen and SoloSTAR are very different.

436. On November 1, 2006, Sanofi filed an NDA pursuant to § 505(b)(2), seeking permission to manufacture, market, and sell a follow-on version of Lilly's Humalog KwikPen, which it proposed to call Admelog. Humalog is one of the rapid-acting insulin analogues – called insulin lispro – distinct from insulin glargine. Sanofi's application disclosed its intention to use the SoloSTAR insulin pen in conjunction with its insulin lispro product.

437. At the time Sanofi proposed to launch an insulin lispro product in its SoloSTAR packaging, the patent over insulin lispro had expired. But Lilly held the '132 patent, which it claimed covered aspects of Lilly's proprietary KwikPen packaging.

438. With its NDA, Sanofi made the required patent certifications pursuant to § 505(b)(2)(A) of the FDCA. Although it had brought and fought an entire lawsuit premised on

the notion that Lilly's KwikPen and Sanofi's SoloSTAR were so similar that one infringed the other's patent, Sanofi now changed its tune. Sanofi sent Lilly a paragraph IV notification letter stating that Lilly's '132 patent was "invalid, unenforceable, or will not be infringed" by Sanofi's Admelog SoloSTAR product.

439. Lilly, of course, agreed that Sanofi's SoloSTAR was a distinct product from Lilly's KwikPen. Lilly could have sued for patent infringement and delayed competition for two-and-a-half years (as Sanofi had), but Lilly did not. That is – Lilly *did not* assert that Sanofi's Admelog SoloSTAR pen infringed Lilly's KwikPen patent.

440. A flummoxed investor confronted Lilly: "You guys have . . . a patent that you could potentially exert and leverage into a delay or maybe a settlement with Sanofi."

441. But, as Lilly's general counsel Michael Harrington responded, "the Hatch-Waxman Act notice process provides an opportunity for a company to *carefully assess* whether a follow-on product infringes patents listed in the Orange Book for a particular product." Harrington noted that "[t]he only remaining Orange Book-listed patent that [Lilly has], that is relevant to this discussion, protects [Lilly's] KwikPen delivery device."

442. Harrington continued:

> [W]e have thoroughly analyzed both the Sanofi device and our own device. Lilly's KwikPen is an innovative device that offers a number of advantages for patients.
>
> But for purposes of analyzing the patents, it's a fundamentally different device than the Sanofi pen that they intend to use with their follow-on [insulin] lispro. We always vigorously defend our intellectual property, and we'll continue to do so aggressively, but we don't engage in litigation to enforce patents unless there is a factual and legal base to do so. *And here, we didn't have a factual and legal basis to support litigation.*[118]

[118] Eli Lilly & Co. (LLY) Q3 2017 Results – Earnings Call Transcript (Oct. 24, 2017), Seeking Alpha, https://seekingalpha.com/article/4116008-eli-lilly-and-co-lly-q3-2017-results-earnings-call-transcript?part=single (last accessed Jan. 31, 2018).

443. The FDA approved Sanofi's Admelog SoloSTAR on December 11, 2017.

W. Sanofi's suits against would-be competitors were motivated by an intent to delay competition.

444. Sanofi's lawsuits against Lilly, Merck, and Mylan were not motivated by a genuine desire to protect its injector pen intellectual property.

445. These suits were intended to – and did – frustrate competition in the market for Lantus and insulin glargine.

446. If Sanofi believed that Lilly's KwikPen infringed Sanofi's initial injector pen patents, it could have – and would have – sued Lilly once Sanofi obtained its first pen patents, in 2011. By that time, Lilly had been selling a product in a KwikPen package (Humalog) for four years. If Sanofi had sued Lilly and prevailed, it would have been entitled to treble damages for each and every unit of Humalog in a KwikPen package that Lilly had ever sold over those years. The prospect of such lucrative damages should have motivated Sanofi to assert its patents then.

447. But money was not Sanofi's only objective. If it had sued Lilly over the Humalog KwikPen packaging in 2011, it would have needed to obtain a judgment on the merits that Lilly's KwikPen infringed Sanofi's patents. Yet this presented two problems.

448. First, for the reasons described above, Sanofi knew it could not expect to succeed in its litigation against Lilly – that is, no reasonable pharmaceutical company would have realistically expected to successfully establish that Lilly's KwikPen infringed Sanofi's polysorbate or injector pen patents. Sanofi would have lost.

449. And second, if Sanofi lost, and had to delist its injector pen patents, it would not have been able to assert that Lilly's KwikPen patent, when used with Basaglar, infringed

Sanofi's patents. In other words, once the '722 formulation patent over insulin glargine expired, Sanofi would have had no way to block competition to its Lantus empire.

450. Sanofi's later suits against Merck and Mylan, too, were nothing but tools to delay competition. In both cases, Sanofi's would-be competitors offered to provide Sanofi would portions of the competitors' § 505(b)(2) applications showing that the products did not infringe any valid, enforceable patent of Sanofi's. Sanofi refused, instead opting to file knee- jerk lawsuits. This is further evidence that Sanofi did not intend the lawsuits to get at the truth of whether its patents stood as barriers to affordable competition to Lantus; it intended only to avail itself of the 30-month stay of competition.

VI. EFFECTS OF THE SCHEME ON COMPETITION AND DAMAGES TO THE PLAINTFFS AND THE CLASS

~~251~~451. Sanofi's impairment of competition was hugely lucrative ~~to Sanofi~~. Sanofi continues to sell Lantus and Lantus SoloSTAR in the United States. It sold approximately $7 billion in Lantus and Lantus SoloSTAR products in 2014. This is hundreds of millions more in sales than Sanofi could have achieved absent its unlawful scheme to impair would-be competition. The entry of Lilly's Basaglar would have driven prices down~~,~~ and ~~/or~~ eaten away at Sanofi's market share.

~~252~~452. Sanofi's overarching anticompetitive scheme impaired and delayed the sale of competing insulin glargine products in the United States, and unlawfully enabled Sanofi to sell Lantus and Lantus SoloSTAR products at ~~artificially inflated~~artificially inflated prices. But for Sanofi's unlawful conduct, Lilly and other competitors would have been able to compete, unimpeded, with Sanofi's Lantus and Lantus SoloSTAR products.

~~253~~453. But for Sanofi's anticompetitive conduct, ~~as alleged above,~~at least one other ~~manufacturers~~manufacturer of insulin glargine products (Lilly) would have entered the

marketplace and ~~effectively~~ competed with Sanofi on or about February 15, 2015, when the pediatric exclusivity associated with Sanofi's Lantus formulation patents expired. But for Sanofi's anticompetitive conduct, another manufacturer (Merck) would have entered the marketplace and competed with Sanofi on or about July 19, 2017, when the FDA granted Merck tentative approval, but could not grant final approval due to the thirty-month stay. Upon information and belief, but for Sanofi's anticompetitive conduct, the FDA will soon tentatively approve Mylan's insulin glargine product; but when it does it will be prohibited from issuing final approval due to the thirty- month stay.

~~254~~454. As a result, were it not for the Sanofi's anticompetitive conduct, the plaintiffs and other members of the class would have: (1) purchased lower-priced insulin glargine products instead of the higher-priced Lantus and Lantus SoloSTAR products for some or all of their insulin glargine needs; (2) paid a lower price for their insulin glargine products, sooner; and/or (3) paid lower prices for some or all of their remaining purchases.

~~255~~455. Had Sanofi not ~~wrongfully~~incorrectly listed patents that did not claim Lantus in the Orange Book, then sued Lilly to block its efforts to obtain § 505(b) approval for a competing insulin glargine product, the market would have embraced Basaglar – which is more cost- effective than Lantus with the same safety and efficacy profile.

~~256~~456. Within months, Lilly would have captured almost all or substantially all sales at lower prices, delivering substantial savings to the plaintiffs and other purchasers. As a result of Sanofi's anticompetitive scheme, however, competition has been very significantly impaired.

~~257~~457. In fact, current events suggest substantial conversion of the market to Lilly's product: after Basaglar entered the market, CVS/Caremark – one of the three largest

PBMs in the country – removed Lantus from its 2017 formulary, and replaced it with Basaglar. Had Sanofi not implemented its wrongful anticompetitive scheme, Lantus would have lost its CVS/Caremark business in February 2015.

458. Had Sanofi not improperly listed the post-2015 injector-pen patents and then sued Merck and Mylan to block those companies' efforts to obtain § 505(b) approval for a competing insulin glargine product, the price of insulin glargine products would have fallen even further.

~~258~~459. During the relevant period, the plaintiffs and other purchasers bought substantial amounts of Lantus. The plaintiffs' and the other purchasers' prices for these products were substantially greater than the prices that they would have paid absent the unlawful conduct alleged herein.

~~259~~460. As a consequence, the plaintiffs and other direct purchasers have sustained substantial losses and damage to their business and property in the form of overcharges, the exact amount of which will be the subject of proof at trial.

VII. MARKET POWER AND MARKET DEFINITION

~~260~~461. At all relevant times, Sanofi had monopoly power in the market for insulin glargine because it had the power to raise or maintain the price of Lantus and Lantus SoloSTAR at supra-competitive levels without losing enough sales to make supra-competitive prices unprofitable.

~~261~~462. At all times relevant to this case, there were only two long-acting, analogue insulin products available in the U.S., insulin glargine and insulin detemir. The products are not equivalent to one another, nor are they interchangeable. As explained above, they are different molecules with different mechanisms of action.

463. Sanofi itself has admitted that there are "many differences between [insulin] Glargine and other forms of insulin," and that "[insulin] Glargine and human insulin are different molecules." Sanofi has described "numerous structural, chemical, and behavioral differences between [insulin] Glargine and human insulin." And in more than one administrative proceeding, Sanofi has criticized any attempt to "conflate[] [insulin] Glargine and non-Glargine insulin."[119]

~~262~~464. A small but significant, non-transitory increase to the price of ~~the~~ Lantus and Lantus SoloSTAR would not have caused a significant loss of sales.

~~263~~465. Lantus and Lantus SoloSTAR do not exhibit significant, positive cross-elasticity of demand with respect to price with any other insulin product other than other insulin glargine products.

~~264~~466. Sanofi needed to control only Lantus and Lantus SoloSTAR and their generic or follow-on equivalents, and no other products, in order to maintain ~~the price of the~~ Lantus ~~franchise~~prices profitably at supra-competitive ~~prices~~levels. Only the market entry of competing, insulin glargine products would render Sanofi unable to profitably maintain their prices for Lantus and Lantus SoloSTAR without losing substantial sales.

~~265~~467. The defendant also sold Lantus and Lantus SoloSTAR products at prices well in excess of marginal costs, and in excess of ~~the~~ competitive ~~price~~prices, and enjoyed high profit margins.

~~266~~468. The defendant has had, and exercised, the power to exclude competition to Lantus and Lantus SoloSTAR.

[119] Opp'n to Petition at 20-25, '652 IPR docket.

~~267~~469. The defendant, at all material times, enjoyed high barriers to entry with respect to ~~the brand and generic~~ Lantus and Lantus SoloSTAR.

~~268~~470. There is direct evidence of market power and anticompetitive effects ~~available~~ in this case sufficient to show Sanofi's ability to control the prices of Lantus and Lantus SoloSTAR.

~~269~~471. There is direct evidence of market power and anticompetitive effects available in this case sufficient to show Sanofi's ability to control the prices of the Lantus and Lantus SoloSTAR products, and to exclude relevant competitors, without the need to show the relevant antitrust markets. The direct evidence consists of, *inter alia*, (a) the fact that competing insulin glargine products would have entered the market at substantial discounts to the brand versions, but for Sanofi's anticompetitive conduct; and (b) the gross margin was at all times substantial enough to show market power, with the price at least 60% higher than the cost of production.

~~270~~472. To the extent proof of monopoly power by defining a relevant product market is required, the plaintiffs allege that the relevant antitrust market is the insulin glargine market.

~~271~~473. The United States, the District of Columbia, and the U.S. territories constitute the relevant geographic market.

~~272~~474. Sanofi's market share in the relevant market was 100% at all relevant times ~~and will remain so~~ until the launch of Lilly's insulin glargine product in or about December 2016.

VIII. MARKET EFFECTS

~~273~~475. Sanofi willfully and unlawfully maintained ~~their~~its market power by engaging in an overarching scheme to exclude competition. Sanofi designed this scheme to delay competition on the merits, for the anticompetitive purpose of forestalling competition against its Lantus product franchise. Sanofi carried out the scheme with the anticompetitive effect of maintaining supra-competitive prices for the relevant product.

~~274~~476. Sanofi implemented the scheme as described herein. These acts, in combination and individually, were undertaken to serve Sanofi's anticompetitive goals.

~~275~~477. Sanofi's acts and practices as described herein had the purpose and effect of restraining competition unreasonably and injuring competition by protecting its Lantus products from competition. These actions allowed Sanofi to maintain a monopoly and exclude competition in the market for Lantus, Lantus SoloSTAR, and other insulin glargine products, to the detriment of the plaintiffs and all other members of the direct purchaser class.

~~276~~478. Sanofi's exclusionary conduct has delayed competition and unlawfully enabled it to sell Lantus and Lantus SoloSTAR products without competition. Were it not for the illegal conduct, one or more competitive insulin glargine products would have entered the market sooner.

~~277~~479. By way of example, and not limitation, in the absence of Sanofi's conduct: (i) a more affordable version of insulin glargine would have become available beginning in or around February 2015, and; (ii) direct purchasers, such as the plaintiffs and other members of the class, would have purchased less supra- competitively-priced Lantus and Lantus SoloSTAR, and instead purchased Lilly's, Merck's and Mylan's less expensive competitor ~~product~~products.

~~278~~480. Sanofi's illegal acts and ~~conspiracy~~scheme to foreclose introduction into the U.S. marketplace of any competing insulin glargine product caused the plaintiffs and all members of the class to pay more than they would have paid for ~~the~~ Lantus products absent this illegal conduct.

~~279~~481. When a competitor drug enters a previously-monopolized market, the price to purchasers drops. As a result, direct purchasers substitute less expensive versions of the drug for some or all of their brand purchases. This price competition enables all direct purchasers of the drugs to purchase competitive products at a lower price, and/or purchase the brand drug at a reduced price. Consequently, brand drug manufacturers have a keen financial interest in delaying the onset of generic competition.

~~280~~482. Thus, Sanofi's unlawful conduct deprived the plaintiffs and members of the class of the benefits from competition that the antitrust laws are designed to ensure.

IX. ANTITRUST IMPACT AND IMPACT ON INTERSTATE COMMERCE

~~281~~483. During the relevant time period, the defendant sold and will sell Lantus and Lantus SoloSTAR across state lines.

~~282~~484. During the relevant time period, the plaintiffs and members of the class purchased substantial amounts of Lantus and Lantus SoloSTAR directly from the defendant, purchased substantial amounts of insulin glargine from Lilly, and will begin to purchase substantial amounts of insulin glargine from ~~Lilly~~Merck and Mylan, once the anticompetitive effects of Sanofi's conduct cease to block those drugs from market. As a result of Sanofi's illegal conduct, as described herein, the plaintiffs and the members of the class were compelled to pay, and did pay, artificially inflated prices for their insulin glargine products, Lantus and Lantus SoloSTAR.

~~283~~485. During the relevant time period, Sanofi used various devices to effectuate the illegal acts alleged herein, including the United States mail, interstate and foreign travel, and interstate and foreign wire commerce. Sanofi engaged in illegal activities, as charged in herein, within the flow of, and substantially affecting, interstate commerce.

X. CLASS ACTION ALLEGATIONS

~~284~~486. The plaintiffs bring this action on behalf of themselves and all others similarly situated under Federal Rule of Civil Procedure 23(a) and 23(b)(3).

> All persons or entities in the United States and its territories, or subsets thereof, that purchased Lantus (in cartridges or ~~Lantus~~ SoloSTAR) directly from Sanofi at any time between February 13, 2015 and December 31, 2016 or until the anticompetitive effects of Sanofi's conduct cease (the "class").

~~285~~487. Excluded from the class are Sanofi and any of its officers, directors, management, employees, parents, subsidiaries, and affiliates.

~~286~~488. Members of the direct purchaser class are so numerous and geographically dispersed that joinder of all members is impracticable. The plaintiffs believe that the class is numerous and widely dispersed throughout the United States. The class is readily identifiable from information and records in Sanofi's possession.

~~287~~489. The plaintiffs' claims are typical of the claims of the members of the class. The plaintiffs and all members of the direct purchaser class were damaged by the same wrongful conduct of the defendant – i.e., as a result of the defendant's conduct they paid artificially inflated prices for ~~the~~ Lantus products.

~~288~~490. The plaintiffs will fairly and adequately protect and represent the interests of the class. The interests of the plaintiffs are coincident with, and not antagonistic to, those of the other members of the class.

~~289~~491. Counsel that represent the plaintiffs are experienced in the prosecution of class action antitrust litigation and have particular experience with class action antitrust litigation involving pharmaceutical products.

~~290~~492. Questions of law and fact common to the members of the class predominate over questions that may affect only individual class members because the defendant has acted on grounds generally applicable to the entire class, thereby making overcharge damages with respect to the class as a whole appropriate. Such generally applicable conduct is inherent in the defendant's wrongful conduct.

~~291~~493. Questions of law and fact common to the class include:

i. Whether the defendant unlawfully maintained monopoly power through all or part of ~~their~~its overall anticompetitive ~~generic~~competition suppression scheme;

ii. Whether the polysorbate formulation patents claimed Lantus cartridges or Lantus SoloSTAR;

iii. Whether Lantus cartridges contained polysorbate 20 or polysorbate 80;

iv. Whether Lantus SoloSTAR contained polysorbate 20 or polysorbate 80;

v. Whether the polysorbate formulation patents could reasonably be asserted against a would-be Lantus competitor, like Lilly;

vi. Whether ~~Sanofi had any~~a reasonable ~~basis to argue~~pharmaceutical manufacturer in Sanofi's position would realistically expect to prove that the polysorbate formulation patents should be enforced against a would-be Lantus cartridge or Lantus SoloSTAR competitor;

vii. Whether Sanofi's assertion of the polysorbate formulation patents against Lilly did in fact frustrate competition;

viii. Whether Lilly's ~~injector pen~~KwikPen infringed the ~~DCA~~initial injector pen patents;

ix. Whether ~~Sanofi had any objectively reasonable basis to argue that the DCA~~Sanofi's initial injector pen patents ~~should be enforced against Lilly~~claimed the finished dosage form of Lantus – i.e., an injectable;

x. Whether Sanofi's initial injector pen patents claimed the active ingredient in Lantus, i.e., insulin glargine;

xi. Whether Sanofi's initial injector pen patents could lawfully be listed in the Orange Book;

xii. Whether a reasonable pharmaceutical manufacturer in Sanofi's position would realistically expect to prove that Lilly's Basaglar infringed the polysorbate and/or pen patents;

xiii. Whether a reasonable pharmaceutical manufacturer in Sanofi's position would realistically expect to prove that Lilly's Basaglar infringed the initial injector pen patents;

~~x~~xiv. Whether Sanofi's assertion of the ~~DCA~~initial injector pen patents against Lilly was intended to frustrate competition;

~~xi~~xv. Whether Sanofi's assertion of the ~~DCA~~initial injector pen patents against Lilly did, in fact, frustrate competition;

xvi. Whether Sanofi's settlement of the Sanofi-Lilly patent litigation preserved Sanofi's ability to assert the initial injector pen patents and vial formulation patents against future would-be competitors;

xvii. Whether Sanofi's post-2015 injector pen patents covered the finished dosage form of Lantus – i.e., an injectable;

xviii. Whether a reasonable pharmaceutical manufacturer in Sanofi's position would realistically expect to succeed on the merits of its suits against Merck and Mylan, given that the asserted patents were improperly listed;

~~xii~~xix. Whether there exist any legitimate procompetitive reasons for some or all of Sanofi's conduct;

~~xiii~~xx. To the extent such justifications exist, whether there were less restrictive means of achieving them;

~~xiv. Whether direct proof of Sanofi's monopoly power is available and, if so, whether it is sufficient to prove Sanofi's monopoly power without the need to define the relevant market;~~

~~xv~~xxi. Whether Sanofi's scheme, in whole or in part, has substantially affected interstate commerce;

~~xvi~~xxii. Whether Sanofi's scheme, in whole or in part, caused antitrust injury through overcharges to the business or property of the plaintiffs and the members of the class;

~~xvii. Whether all of the defendants conspired to suppress competition for Lantus cartridges or Lantus SoloSTAR;~~

~~xviii~~xxiii. Whether, in the absence of Sanofi's anticompetitive conduct, Lilly's competing insulin glargine product would have entered the market on or around February 15, 2015;

xxiv. When, in the absence of Sanofi's anticompetitive conduct, additional competing insulin glargine products would have entered the market earlier;

~~xix~~xxv. Whether, as a result of Sanofi's anticompetitive conduct, direct purchasers were overcharged for their insulin glargine purchases;

~~xx~~xxvi. Whether Sanofi's anticompetitive conduct was a substantial contributing factor in causing delayed availability of competing insulin glargine ~~products~~;

~~xxi~~xxvii. A reasonable estimate the delay occasioned by Sanofi's wrongful conduct; and

~~xxii~~xxviii. The quantum of overcharges paid by the class in the aggregate.

~~292~~494. Class action treatment is a superior method for the fair and efficient adjudication of the controversy. Such treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, or expense that numerous individual

actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities a method for obtaining redress on claims that could not practicably be pursued individually, substantially outweighs potential difficulties in management of this class action.

~~293~~495. The plaintiffs know of no special difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

XI. CLAIMS FOR RELIEF

COUNT ONE – MONOPOLIZATION IN VIOLATION OF SECTION 2 OF THE SHERMAN ACT

(15 U.S.C. § 2)

(Overall Monopolization Scheme)

~~294~~496. The plaintiffs hereby repeat and incorporate by reference each preceding and succeeding paragraph as though fully set forth herein.

~~295~~497. At all relevant times, Sanofi possessed monopoly power in the relevant market and possessed the power to raise and maintain supracompetitive prices and exclude competitors from the relevant market.

~~296~~498. The defendant engaged in an exclusionary conduct scheme that included at various times each of the following acts (among others):

i. Improperly listing the '652 patent in the Orange Book as covering Lantus cartridges and Lantus SoloSTAR;

ii. Improperly listing the '930 patent in the Orange Book as covering Lantus cartridges and Lantus SoloSTAR;

iii. Improperly listing the '833 patent in the Orange Book, when it did not claim a drug substance, drug product, or method of using a drug;

iv. Improperly listing the '297 patent in the Orange Book, when it did not claim a drug substance, drug product, or method of using a drug;

v. Improperly listing the '864 patent in the Orange Book, when it did not claim a drug substance, drug product, or method of using a drug;

vi. Improperly listing the '044 patent in the Orange Book, when it did not claim a drug substance, drug product, or method of using a drug; ~~and~~

vii. Commencing and maintaining a sham litigation against Lilly to delay introduction of competing insulin glargine products into the U.S. market.;

viii. Improperly listing and asserting the thirteen additional pen patents; and

ix. Commencing additional lawsuits against would-be competitors to further impede competition in the market for insulin glargine.

499. Sanofi's suit against Lilly was objectively baseless and motivated by a subjective desire to delay competition in the insulin glargine market.[120]

500. Sanofi engaged in a pattern of anticompetitive petitioning for which it is independently liable under federal antitrust law, even if each act of petitioning is not independently objectively baseless.[121]

501. Sanofi improperly submitted its pen patents for listing in the Orange Book despite the fact that they failed the first part of the regulatory test: they did not claim the

[120] *Professional Real Estate Invstors, Inc. v. Columbia Pictures Indus., inc.*, 508 U.S. 49 (1993).

[121] *California Motor Transportation Co. v. Trucking Unlimited*, 404 U.S. 508 (1972); *See Hanover 3201 Realty, LLC v. Vill. Supermarkets, Inc.*, 806 F.3d 162, 179 (3d Cir. 2015), *cert. denied sub nom., Vill. Supermarkets, Inc. v. Hanover 3201 Realty, LLC.*, 136 S. Ct. 2451 (2016); *Waugh Chapel S., LLC v. United Food & Commercial Workers Union Local 27*, 728 F.3d 354, 363-64 (4th Cir. 2013); *Primetime 24 Joint Venture v. Nat'l Broad. Co.*, 219 F.3d 92, 100-01 (2d Cir. 2000); *USS-POSCO Indus. v. Contra Costa Cnty. Bldg. & Constr. Trades Council, AFL-CIO*, 31 F.3d 800, 810-11 (9th Cir. 1994); see also *Puerto Rico Tel. Co., Inc. v. San Juan Cable LLC*, 874 F.3d 767, 773 (1st Cir. 2017) (Barron, J. concurring) ("[W]e do not hold that the 'objectively baseless' requirement for triggering the sham exception set forth in the single-petition case of *Professional Real Estate Investors*, necessarily applies to each and every case involving a pattern of petitioning. We instead rely on a more record-based, case-specific line of reasoning that, as I read our opinion, leaves open the possibility that, *PREI* notwithstanding, a monopolist might be liable under the antitrust laws for engaging in a pattern of petitioning, even though no single filing in that pattern is objectively baseless." (internal citation omitted)).

finished product with an active ingredient. There is no "reasonableness" defense available to Sanofi.

~~297~~502. The goal, purpose, and/or effect of Sanofi's scheme was to maintain and extend its monopoly power with respect to insulin glargine products – sold under the brand names Lantus and Lantus SoloSTAR. Sanofi's illegal scheme to prevent, delay, and/or minimize the success of the introduction into the United States marketplace of any competing versions of the insulin glargine products enabled Sanofi to continue charging supra-competitive prices for the products without a substantial loss of sales.

~~298~~503. If manufacturers of competing insulin glargine products had not been prevented by Sanofi from entering the market, the plaintiffs and members of the class would have purchased lower-priced insulin glargine products for some or all of their insulin glargine product requirements, and/or would have received lower prices on some or all of their remaining Lantus or Lantus SoloSTAR purchases, at earlier periods of time and in far greater quantities.

~~299~~504. As a result of Sanofi's illegal scheme, the plaintiffs and the class paid more than they would have paid for insulin glargine products, absent the illegal conduct. But for the illegal conduct, competitors would have begun marketing competing versions of insulin glargine, resulting in cost savings to the plaintiffs and direct purchasers.

~~300~~505. During the relevant period, the plaintiffs and the class purchased substantial amounts of Lantus and Lantus SoloSTAR directly from Sanofi. As a result of Sanofi's illegal conduct, the plaintiffs and the members of the class were compelled to pay, and did pay, ~~artificially inflated~~artificially inflated prices for their insulin glargine product requirements. The plaintiffs and all class members paid prices for Lantus and Lantus

SoloSTAR that were substantially greater than the prices that they would have paid absent the illegal conduct alleged herein, because: (a) class members were deprived of the opportunity to purchase lower-priced drugs instead of expensive Lantus and Lantus SoloSTAR; and/or (b) the price of Lantus and Lantus SoloSTAR was artificially inflated by Sanofi's illegal conduct.

~~301~~506. The anticompetitive consequences of Sanofi's actions far outweigh any arguable procompetitive benefits. Sanofi acquired and extended a monopoly through unlawful means.

~~302~~507. Sanofi's scheme was, in the aggregate, an act of monopolization undertaken with the specific intent to monopolize the market for insulin glargine products in the United States, in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

COUNT TWO – ATTEMPTED MONOPOLIZATION IN VIOLATION OF SECTION 2 OF THE SHERMAN ACT

(15 U.S.C. § 2)

(Attempted Overall Monopolization Scheme)

~~303~~508. The plaintiffs hereby repeat and incorporate by reference each preceding and succeeding paragraph as though fully set forth herein.

~~304~~509. At all relevant times, Sanofi possessed substantial power (i.e., monopoly power) or possessed a dangerous probability of achieving monopoly power.

~~305~~510. With the specific intent to achieve a monopoly, Sanofi attempted to acquire and/or willfully maintain monopoly power by means of restrictive or exclusionary conduct, rather than by means of greater business acumen, in order to exclude competition for insulin glargine products.

~~306~~511. The goal, purpose, and effect of Sanofi's conduct was to delay and impair the sale of competing insulin glargine products in the United States at prices below Sanofi's

prices for Lantus and Lantus SoloSTAR, thereby effectively preventing the average market price for Lantus, Lantus SoloSTAR, and their follow-on products from declining dramatically.

~~307~~512. By engaging in the foregoing conduct, Sanofi has intentionally and wrongfully attempted to monopolize the relevant market in violation of the Sherman Act.

~~308~~513. But for Sanofi's unlawful conduct, other manufacturers would have launched competing insulin glargine products.

~~309~~514. The plaintiffs and members of the class have been injured in their business or property by reason of Sanofi's antitrust violations alleged herein. Their injuries consist of: (a) being denied the opportunity to purchase lower-priced insulin-glargine products; and (b) paying higher, supra-competitive prices for Lantus and Lantus SoloSTAR than they would have paid in the absence of Sanofi's conduct. These injuries are of the type the Sherman Act was designed to prevent, and flow from that which makes Sanofi's conduct unlawful.

~~XII.~~ DEMAND FOR JUDGMENT

~~310~~515. WHEREFORE, the plaintiffs, on behalf of themselves and the proposed class, respectfully demand that this Court:

a. Determine that this action may be maintained as a class action pursuant to Federal Rules of Civil Procedure 23(a) and (b)(3), and direct that reasonable notice of this action, as provided by Federal Rule of Civil Procedure 23(c)(2), be given to the class, and declare the plaintiffs as the representative of the class;

b. Enter ~~joint and several judgments~~judgment against the defendant and in favor of the plaintiffs and the class;

c. Award the class damages (i.e., three times overcharges) in an amount to be determined at trial;

d. Award the plaintiffs and the class their costs of suit, including reasonable attorneys' fees as provided by law; and

e. Award such further and additional relief as the case may require and the Court may deem just and proper under the circumstances.

~~XIII~~XII. JURY DEMAND

~~311~~516. Pursuant to Fed. Civ. P. 38, the plaintiffs, on behalf of themselves and the proposed class, demand a trial by jury on all issues so triable.

Dated: ~~March 30, 2017~~ ~~Respectfully submitted,~~February 20, 2018

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CERTIFICATE OF SERVICE

I, Thomas M. Sobol, certify that, on this date, the foregoing document was served by filing it on the court's CM/ECF system ~~and additionally via electronic mail~~, which will automatically send a notification of such filing to all counsel of record via electronic mail.

Dated: ~~March 30~~February 20, ~~2016~~2018

/s/ Thomas M. Sobol
Thomas M. Sobol